U.S. ENVIRONMENTAL PROTECTION AGENCY, REGION 2

July 10, 2018

BY ELECTRONIC MAIL

Robert Law, Ph.D.
de maximis, inc.
186 Center Street, Suite 290
Clinton, New Jersey 08809

Re: Re: Lower Passaic River Study Area Revision 2 Draft Baseline Ecological Risk Assessment (Agreement) CERCLA Docket No. 02-2007-2009

Dear Dr. Law:

The U.S. Environmental Protection Agency (EPA) has reviewed the Lower Passaic River Study Area (LPRSA) Revision 2 Draft Baseline Ecological Risk Assessment (BERA), dated December 29, 2017 prepared by Windward on behalf of the Cooperating Parties Group (CPG) for the LPRSA Remedial Investigation/Feasibility Study. Most of the revisions requested by EPA on the October 7, 2016 draft of the BERA, and the revisions discussed in our subsequent calls and meetings have been satisfactorily addressed.

EPA and CPG cooperatively developed a list of Toxicity Reference Values (TRVs) for use in the October 7, 2016 draft of the BERA. In the Revision 2 Draft BERA, CPG included new TRVs for several chemicals. Because the TRV issues has already been resolved, EPA will require that the new TRVs use the EPA's default TRV approach as follows:

- TRVs that are not bounded (having both a no observed adverse effect level (NOAEL) and a lowest observed adverse effect level (LOAEL)) will use a factor of ten to go from LOAEL to NOAEL (LOAEL/10), as is specified in EPA's Ecological Risk Assessment Guidance for Superfund (ERAGS)
- The species sensitivity distribution (SSD) approach uses multiple studies, and selection of a NOAEL from a study that is not associated with the selected SSD LOAEL is not valid.

EPA and CPG have discussed appropriate statistical methods for the multivariate analyses required to relate contaminants to benthic invertebrate impacts. The results of the analyses provide the basis to draw meaningful conclusions, but the conclusions have not been elucidated in the Revision 2 Draft BERA, therefore, EPA has provided additional guidance.

Comments from the partner agencies have been incorporated into this memo. Please proceed with revisions to the draft Revision 2 BERA within 30 days consistent with the enclosed comments. If there are any questions or clarifications needed, please contact me to discuss.

Sincerely,

Diane Salkie, Remedial Project Manager
Lower Passaic River Study Area RI/FS

Enclosure

Cc: Zizila, F. (EPA)
Sivak, M. (EPA)
Hyatt, B. (CPG)
Otto, W. (CPG)

No.	Location/ Page No.	EPA Comments on 10/7/16 Revised Draft BERA	EPA Comments on 12/29/17 Revision 2 Draft BERA
1	General Comment	The same salinity zones should be used for the Sediment Quality Triad as for the rest of the BERA. It is inappropriate to use salinity measurements from one point in time to change the salinity zones solely for the benthic evaluation. Revise the text throughout the BERA to use consistent terminology when referring to salinity zones.	Revision is acceptable.
2	General Comment	Every table that includes TEQs and every section that discusses TEQs must specify which TEQ (fish, avian, mammal) is being referenced.	Revision is acceptable.
3	General Comment	Any discussion of the uncertainty associated with the TEQ methodology belongs in the uncertainty section of the risk characterization.	Revision is acceptable.
4	General Comment	Evaluation of PAHs in sediment should be based on EPA's toxic unit approach – calculated for 34 PAHs. While the PAH-34 ESB TU results are summarized in Appendix P, the results should also be discussed in the risk characterization of the BERA.	Revision is acceptable.
4a	General Comment	-no comment on 2016 draft-	The Revision 2 Draft BERA uses twelve citations for "Windward [in prep]" documents (a through l), all of which, except "l", are listed in the References stating that they were submitted as draft documents to EPA either in 2013 or in 2015. These documents have not been finalized or accepted by EPA as final and therefore, should not be used as a citation as the documents that relate to statements in the BERA may change. EPA is conducting a more in-depth review of the status of the "in prep" documents in an effort to provide input so that they can all be finalized. EPA requests that the CPG should also review the status of the "in prep" documents to identify any outstanding issues.

			EPA would like to have a call or meeting to discuss the disposition of the "in prep" documents to develop a path forward for finalization, which will allow their use as citations in the BERA. For the "in prep" documents that contain data or information used to support BERA statements, it may be more appropriate to include this information in the BERA or in an appendix, so that it is readily accessible in the final BERA for reviewers and readers. Also note that of the twelve references cited in the Reference section, only seven are cited in the text of the report.
5	Page ES-4, last sentence before Table ES-1	Replace "chemistry" with "concentrations of sediment contaminants"	Revision is acceptable
6	Page ES-7, Table ES-2	In the "Benthic invertebrate community" receptor row, the last column, first bullet states that no, low, or likely low impacts were observed at ~36% of the 97 SQT locations. This bullet should state that, "Impacts were observed at ~64% of the 97 SQT locations."	Unacceptable. Table ES-2 and the text associated with this comment (on page ES-13) were not revised. In addition, in the other part of the report, such statement should also be revised (i.e., Table ES-4, page ES-38, page 249, and Tables 13-1 and 13-3).
7	Page ES-7, Table ES-2	In the "Benthic invertebrate community" receptor row, the last column, third bullet states that "…risk was relatively unclear (medium impact) due to the possible influence of urban stressors…" The variable measured in the BERA was the inclusion of site-related contaminants to receptor exposures. It is unlikely that the impacts were unrelated to site-related releases. The assertion that impacts are due to urban stressors is not supported, and should not be included in the BERA.	Unacceptable. The revision was not made (now Table ES-1 on page ES-3). Delete the phrase "…due to the possible influence of urban stressors, which were not associated with the site-related release of hazardous materials."
8	Page ES-12, "Lead" bullet	Comparison of site EPCs to background should not be limited to background maximum concentration. This equates to comparing site mean or 95% UCLs to background maximum, which is not appropriate. This is a global comment for the entire document.	Revision is acceptable.
9	Page ES-22, last sentence of first	Revise the text to include all potential receptors, regardless of the focal vs non-focal classification.	Revision is acceptable.

	paragraph of Section ES.6.3.2 Fish	Further, regardless of focal/non-focal, these species should be identified based on trophic status (omnivore, invertivore, piscivore).	
10	Page 15, Section 2.1.1, second paragraph	While it is important to point out environmental "factors" that influence ecological communities, chemical contamination must be identified as a major stressor and the focus of this BERA.	Revision is acceptable.
11	Page 21, Section 2.1.1.3	The BERA failed to address comment 21 from the original comment set (EPA 5/1/2015 response to comments matrix). The focus on turbidity due to carp presence is overstated. Carp are not the only environmental stressor, and should not be portrayed as such. Their importance in food web dynamics is far more important than their contribution to turbidity, and should be discussed. Additionally, the tidal movement of the salt wedge disturbing the entire river bottom four times per day is a much greater disturbance than any biological activity.	Revision is acceptable.
12	Page 25, Section 2.1.1.7, last paragraph	The discussion of the role of avoidance by biota should be expanded based on the listed references confirming this behavior when exposed to multiple types of chemical contaminants.	Revision is acceptable.
13	Page 26, Section 2.1.1.7, second paragraph	There is doubt that DO is most influenced by salinity. In a larger, tidal system, there will be daily fluctuations in DO. However, larger-scale trends in DO will be seasonal and subject to nutrient inputs and BOD. The CPG has addressed the comment by including historical data and trends, but this discussion appears to be used to support salinity being the primary control on ecological communities. CPG presents this paragraph as if salinity has the greatest control on DO. While salinity does influence DO, so do nutrient loading, seasonal temperature fluctuations, and algae/macrophyte communities.	Unacceptable. The comment was not addressed. The text still states that salinity is the primary cause of decreased DO. The support for this statement is listed as (Windward [in prep]-j), a document which has not been finalized. See Comment 4a. It is a fact that salt water has a lower saturation level for DO than does fresh water. However, a drop in DO from saturated freshwater to saturated salt water is not an ecological concern, as organisms that live in the transition zone are adapted to such changes. A significant drop in DO (with the potential for adverse impacts) is not likely to be caused simply by a change from fresh to salt water. The DO depression has to be caused by some environmental factor (e.g., nutrient loading). Revise the text to replace the last paragraph in Section 2.1.1.7 with the following:

		These other factors should also be included in the discussion	"Periodically depressed DO concentrations in the LPRSA may have been the result of several biotic (e.g., BOD) and abiotic (e.g., temperature and salinity) factors. Available data do not include BOD, so the relationship between BOD and DO currently cannot be determined. Higher salinity and lower DO concentrations were observed at monitoring locations in estuarine waters than at locations in freshwater areas (Windward [in prep]-j). However, salt water has a lower saturation level for DO than does freshwater. A tide-related drop in DO from saturated freshwater to saturated salt water is not an ecological concern, as organisms that live in the transition zone are adapted to such changes."
14	Page 26, Section 2.1.1.8	More site-specific data are provided, but it is not likely that carp are responsible for loss of SAV, and a shift in benthic and algae communities. While it is possible that carp can contribute to this situation, it's doubtful that they are entirely or even primarily responsible. Revise the text.	Revision is acceptable.
15	Page 26, Section 2.1.1.8, first complete paragraph	This whole discussion ignores the fact that carp are routinely found in aquatic systems nationwide with diverse and abundant fish communities. Adverse effects of carp are more likely to be localized, minimal, and most apparent in lentic systems. Revise all carp-related text to remove language inferring that carp are a leading contributor to impacted habitat conditions in LPRSA.	Revision is acceptable.
16	Page 42, Section 2.1.2.2, first paragraph	The species name for eastern cottonwood is *deltoides.*	Revision is acceptable.
17	Page 42, Section 2.1.2.2, second paragraph	Check parentheses around "elm". Also, verify that genus name of purple loosestrife has been presented previously (i.e., spelled out).	Revision is acceptable.
18	Page 45, Section 2.2.1	There are concerns regarding discussions of habitat/environmental controls on biota in the absence of chemical contamination. Throughout these sections controls are discussed as they would exist in	Revision is acceptable.

		non-contaminated systems. For example, it is recognized that salinity matters, but chemical contamination also has a role which should be discussed. Salinity is not a significant stressor, as it would only be an issue in the transition zone, where the biota are adapted to living with variable salinity, and would not be stressed. All other stressors should be discussed together in a complete and balanced presentation, as all can contribute to current conditions.	
19	Page 48, Section 2.2.1.1	Revise the text to include discussion of benthic burrowing depths/trends, and provide benthic survey data and results in associated appendix. Add a column to Table 2-3 with burrowing depths. References previously provided by EPA pertaining to burrowing depths of benthic invertebrates should be included in the BERA: *Esselink and Zwarts. 1989. Seasonal trend in burrow depth and tidal variation in feeding activity of Nereis diversicolor. Mar. Ecol. Prog. Ser. Vol. 56: 243-254, 1989* *Kristensen and Kostka. 2000. The Ecogeomorphology of Tidal Marshes. Coastal and Estuarine Studies 59. Copyright 2004 by the American Geophysical Union*	Revision is acceptable, though the two references were not included. Please include these references.
20	Section 2.2.1.1	This section presents summaries of the major benthic taxa observed during the field surveys performed (fall 2009, spring 2010 and summer 2010). Where available, this same information should be presented for the various reference locations used for the benthic community evaluations as part of the SQT (not readily found in Section 2, 6 or associated appendices).	Partially acceptable. The information is in tabular form in Appendix L, but in that format, it cannot be compared to the figures and text in Section 2.2.1.1. Though the Reference Area data was collected by others, if it is to be used for comparison purposes, the tabulated Reference data should be presented in parallel with the Study Area data. The section should also include figures similar to Figures 2-10, 2-11, 2-12, 2-13, 2-14, 2-15, and 2-16 for the reference area data above Dundee Dam, in the Mullica River, and in Jamaica Bay (or where

			appropriate, the reference data can be added to the existing figures). The current figures are good representations of the site, but their value is diminished without comparison to the reference areas.
21	Page 54, Section 2.2.1.1, last paragraph	Although salinity is a key factor in relative abundance, this discussion would benefit by adding that other factors can significantly contribute to relative abundance. These include particle size, DO, etc., as well as sensitivity to contaminants. Dominance of dipterans and oligochaetes is a common finding in nutrient enriched waters AND in waters with significant chemical contamination. Revise the text to include other potential factors that influence relative abundance.	Revision is acceptable.
22	Page 57, Section 2.2.1.2, third paragraph	Temperature should be included as a factor that can affect diversity shifts (in addition to flow).	Revision is acceptable.
23	Page 58, Section 2.2.1.3, first paragraph below bullets	The classifications of the dominant feeding modes of benthic species were discussed during the development of the bioaccumulation model parameters, and needs more support in this section of the BERA. It is unclear why filter feeders are included under the detritivore feeding guild. It does not appear that feeding mechanisms are correctly identified for the various benthic macroinvertebrates. True deposit feeder can be selective or not, but these organisms feed on and through sediment deposits - ingesting sediments and extracting organics/nutrients in their gut. Some organisms remain in place (buried within the sediments and often in a mucus lined burrow) to deposit feed (e.g. lug worm, *Arenicola*) while some plow through sediment akin to earthworms. True detritivores feed on free organic, particulate	Revision is acceptable.

		material. Often this is thought of as organic “debris” or detritus. Grazers, such as many herbivorous snails, feed on living, intact organisms such as edaphic (on surfaces of rocks or other substrata) algae, epiphytes, diatoms, bacteria, etc. Also consider the common ragworm, *Alitta succinea* that is both infaunal and epifaunal collective "food from the surface and below the sediment surface) (this species is omnivorous). Snails that tear algae or plants or rasp holes in them, are herbivores. Filter feeders feed on particulates and small organism within the water column by straining organics, particles and/or plankton in an intact functional “net” composed of tentacles, radioles, etc. or with constructed mucous entrapment “webs” or sticky tentacles, etc.). While they might trap detrital particulates, the major difference is that they feed out of the water column. Here too there are selective and non-selective filter feeders. Bivalves certainly fall in the selective range. And, since *Corbicula* is an important player in the freshwater portions of the river, this clam is mainly a filter feeder but is capable of using its foot to deposit feed. Some believe that when food in the water column is scarce, *Corbicula* will acquire additional nutrients via pedal feeding. For classification of invertebrates, see attached spreadsheet.	
24	Page 59, Section 2.2.1.3, first paragraph	Discussion is focused on predators and parasites as factors affecting community structure, but this discussion ignores the role of chemical contamination. Revise the text to include the potential role of contamination.	Revision is acceptable.
25	Page 59, Section 2.2.1.3, Figure 2-19	There remains some question regarding appropriate feeding guilds for some organisms. Revise this text	Revision is acceptable.

		based feeding guild discussions held with Dr. Robert Prezant (Montclair State University) for the bioaccumulation modeling on 8/5/16. See attached invertebrate classification spreadsheet.	
26	Page 62, Section 2.2.1.3, Figure 2-22	Confirm in the text that abundance figures are based on count data, and not on estimated weight data (biomass).	Revision is acceptable.
27	Page 69, Section 2.3, first paragraph	Feeding guilds can change over lifetime (some are invertivores when young, becoming herbivores or piscivores at later life stages.). This should be discussed.	Revision is acceptable.
28	Page 72, Section 2.3.2, third to last paragraph	Ictalurids have comparable feeding behavior to carp, yet are not identified as taxa that can degrade or impair habitat. Revise the text to include a discussion of ictalurids.	Partially acceptable. The revision was not included, but Section 2.1.1.8 included text saying that catfish disturb sediment like carp. Revise the second-to-last paragraph in Section 2.3.1 to read: "Common carp eat a wide variety of aquatic plants…They usually feed by rooting in the bottom substrate with their snouts, eating the food they dislodge, along with fine sediment and detritus (Pennsylvania FBC 2011). *It should also be noted that catfish, through their behavior and use of bedded sediment as habitat, can also disturb sediment, as can other benthic feeding native species such as suckers.* Adult common carp are opportunistic feeders…"
29	Page 77, Section 2.3.6, last bullet	Since carp make up a large portion of the fish catch, they should be included in the discussion as a significant aquatic receptor.	Acceptable.
30	Page 78, Section 2.3.6, first complete paragraph	This discussion identifies many benthic feeders, but only carp are extensively discussed as being destructive based on feeding strategy. As written, the text is biased, and should be revised.	Revision is acceptable.
30a	Page 67, Section 2.3.6, Figure 2-17	-no comment on 2016 draft BERA-	Figure 2-17 is a representation of the fish collected in the LPRSA. Figure 2-17 is appropriate, but of limited value unless a similar figure is produced for the reference locations. Add another figure, similar to Figure 2-17, that depicts the reference area fish abundance.

31	Page 78, Section 2.3.6, first paragraph	The text discusses a "shorter, simpler food chain". The references all refer to nitrogen and carbon isotopes which were not measured for this site. A more appropriate reference would be discussion would be Post, DM, 2002. *The Long and Short of Food Chain Length*. Trends in Ecology & Evolution, vol 17, #6, which explains that systems with frequent disturbances (e.g., salt wedge) tend to have shorter food chains.	Revision is acceptable.
32	Page 81, Section 2.4, fifth bullet	Revise "aquatic birds" to "aquatic-feeding birds".	Revision is acceptable.
33	Page 83, Section 2.4.4	a. The Great Blue Heron feeds on fish, in addition to the other prey listed in this section. Correction needed. b. For the remaining wading birds of the LPRSA, types of prey need to be identified.	Revision is acceptable.
34	Page 87, Section 2.6	Latin name (species) of snapping turtle is *serpentina.*	Revision is acceptable.
35	Page 93, Section 3	This section requires revision because it does not directly describe the main "problem" under study: chemical contamination. The opening two paragraphs emphasize the relevance of the urban/industrial setting of this river on the health of the LPRSA ecosystem, without also discussing the focus of this BERA per CERCLA, that of chemical contamination and its pervasiveness in media of this river's ecosystem. Section 3 should be revised to present a more balanced description of chemical risks to ecological receptors.	Revision is acceptable.
36	Section 3.2, Table 3-2	The table should also include species that CPG has relegated to being non-focal. All ecological receptors should be included in the BERA.	Revision is acceptable.
37	Page 109, Section 4.1, Table 4-1	The Data Quality Objectives do not include "data must represent current conditions" since the selected	Revision is acceptable

		"reference" and "background" locations do not meet this objective. The text should be revised to say that data must define current conditions.	
38	Page 112, Section 4.2.2, last complete sentence	This sentence is not accurate generally. If this is a site-specific observation (2 cm burying depth), it should be noted as such. References provided within the 2-cm dispute resolution clearly show varying burrowing depths among taxa (June 7, 2016). Further, referencing only the top 2 cm is inappropriate, and sediment toxicity data should be inclusive of the top 15-cm. All unsupported speculation regarding chemical concentrations in the upper 2 cm of sediment that is included in sections outside of the uncertainties sections (e.g., pp 112-113) must be removed from the report.	Unacceptable. The last sentence in the first paragraph of Section 4.2.2 still states, "…the LPRSA benthic invertebrate community is dominated by fairly shallow-dwelling deposit feeders and detritivores…" This statement is misleading and must be deleted, and the text revised to reflect the resolution of the 2cm dispute (June 7, 2016 EPA position letter to demaximis, and the June 28, 2016 EPA Dispute Resolution letter to demaximis). The issue of benthic invertebrate exposure depth has been dealt with through formal dispute resolution, through a thorough set of comments on the BERA (June 30, 2017 EPA comments on the October 7, 2016 Draft BERA), and through multiple conference calls and meetings. The statement should read "…the LPRSA benthic invertebrate community is dominated by deposit feeders and detritivores…" Delete references to shallow-dwelling here and globally throughout the BERA.
39	Page 125, Section 4.2.2, Figure 4-5	Correction needed for location of the SQT designated as "remediated" in vicinity of OU1. Current location shown is in the Phase II Removal area for which remedial action has not been performed, therefore not remediated.	Revision is acceptable.
40	Page 130, Section 4.2.3, Table 4-3	Footnote "c" does not seems related to this item (or other fish with superscript "c"). Revise the footnote to clarify.	Unacceptable. The revision was not made. It appears that the footnote is saying 14 L. variegatus samples were analyzed, but the footnote says that one sample (LPRT11E) was collected in the RM 10.9 dredge area. Clarify the footnote – were there initially 15 samples and the tissue exposed from LPRT11E was not utilized, were there 14 samples including the LPRT11E sample, or were there 14 samples because the LPRT11E sample was excluded?
41	Page 208, Section 4.3.2	These concluding statements must be appropriately reflected in Section 4.2.3 by adding a concluding statement such as: "Despite some inherent uncertainties, the TEQ methodology provides a reasonable, scientifically justifiable, and widely	Revision is acceptable.

		accepted method for estimating risks to ecological receptors in CERCLA risk assessments." (EPA, 2008). Reference: EPA, 2008. *Framework for Application of the Toxicity Equivalence Methodology for Polychlorinated Dioxins, Furans and Biphenyls in Ecological Risk Assessment*.	
42	Page 211, Section 4.3.5	Where biological tissues were normalized for lipids, the data should be summarized here.	Revision is acceptable.
43	Page 234, Section 5.5.3.1	Clarify or remove the following statement: "The toxicity of 2,4-D to benthic invertebrates in sediment is also considered low". Toxicity of 2,4-D to BMI is highly variable in its different forms. Delete the phrase "is also considered low". The toxicity of 2,4-D should be assessed in the Revised BERA using the SQT approach.	Revision is acceptable.
44	Page 235, Section 5.5.3.3, paragraph below first bullet	Revise the text to include LOAEL-based HQs for endrin in fish tissues since one-third of the samples exhibited exceedances (HQ>1). Text should be revised so as not to downplay the significance of this finding.	Revision is acceptable.
45	Page 240, Section 6, Table 6-1	Regarding the sediment toxicity testing, the table states that this LOE is located in Appendix P, Section 1.2. In fact, it is Appendix P, Section 3. Please correct this and add additional information to this table to direct the reader to other/all appendices with supporting information. For example, Appendices B, L, and K contain important data, tables, and figures relevant to the Sediment Toxicity LOE.	Revision is acceptable.
46	Page 245, Section 6.1.2.1, first incomplete paragraph	Revise the text to indicate whether all Jamaica Bay data were used, or whether data from apparently contaminated areas of Jamaica Bay removed prior to establishing reference conditions. Footnote on Table 6-7 should be non-urban.	Revision is acceptable.
47	Page 246, Section 6.1.2.2	Text needs to be revised to reflect that finding of "medium impact" does not necessarily suggest unclear	Revision is acceptable.

		or unknown results. It may indicate that there are moderate impacts (either moderate in severity, or a moderate chance of adverse effects).	
48	Page 247, Section 6.1.2.2, Flow Chart	On the flow chart, revise to remove the reference to CSOs, as the "stressful habitat" is defined in the footnote to the chart as being related to ammonia, TOC, or total fines, and not to the presence or absence of CSOs. Additionally, there are only three outcomes from the flow chart but six categories in Table 6-8. The flow chart and table should be consistent.	Revision is acceptable.
49	Page 249, Section 6.1.2.2, third sentence in first paragraph	Results suggest 30 stations are described as indeterminate, but these can also be described as moderately impacted. Text needs to be updated to reflect this.	Revision is acceptable.
50	Page 249, Section 6.1.2.2, end of first paragraph	CPG should place less emphasis on SEM-AVS findings, and should discuss the uncertainty associated with the analysis. SEM-AVS is a highly variable analysis (primarily due to inconsistent results from laboratories, based on split sample analyses) and may not accurately reflect bioavailability of metals. It is one line of evidence, but should not be used to stand alone.	Revision is acceptable.
51	Page 253, Section 6.1.3, second bullet	Change "maybe" to "may be".	Revision is acceptable.
52	Pages 253 to 254, Section 6.1.3, last bullet	The relationship between the probability of sediment toxicity (T-values) and the magnitude of response (amphipod survival) is addressed in EPA 2005. The following statement should be removed: "The logistic modeling approach used to derive T20 and T50 values does not address the magnitude of the relationship between concentration and "toxic" response. Therefore, it is not possible to determine what level of effect can be expected (i.e., what magnitude of risk to invertebrates) from exceedances of T20 and T50 values".	Revision is acceptable.

		However, if the CPG considers these values to be uncertain, then text can be added to the uncertainty section.	
53	Page 254, Section 6.1.3, third bullet	Sediment chemistry LOE may over-predict risks, as noted, due to reduced bioavailability of contaminants in sediment. However, this LOE may also under-estimate risks because cumulative toxicity from simultaneous exposure to multiple contaminants is for the most part not considered. It is therefore more accurate to state that the sediment chemistry LOE is more uncertain than the toxicity test or community LOEs. Revise the text.	Revision is acceptable.
54	Page 257, Section 6.1.3.1, first paragraph	Data presented show 25% medium or high impact, which is significant, especially given the uncertainties noted. Risks may be higher or lower than those suggested by these findings, and statements that BMI are "generally not impacted…" are not defensible. This statement needs to be revised to state the importance of 25% having medium or high impact, or the statement suggesting that BMI are "generally not impacted" needs to be removed. Additionally, the four impact levels should be also discussed separately on a reach by reach basis, and not just discussed as a site-wide combined exposure.	Revision is acceptable.
55	Page 258, Section 6.1.4, second bullet	Revise the text to reflect that medium impact is not necessarily equal to uncertain results. It may equate to medium level impacts (or a moderate potential for ecologically significant adverse effects). Additionally, the second bullet on page 258 says 54% were medium impacts, but the comment above says only 25% were medium or high, the numbers should be revised so the text matches the tables.	Revision is acceptable.
56	Page 258, Section 6.1.4, third bullet	Stated shift is really for only a few more locations. This should be clarified or eliminated.	Revision is acceptable.
57	Page 267, Section 6.2.3.1, Table 6-16	It is unclear whether TRVs for metals are based on inclusion or rejection of toxicity data for daphnids.	Revision is acceptable.

		Surface water TRVs are stated to be used for evaluation of zooplankton, but this specific evaluation is for BMI. It is recommended that daphnid-based toxicity data be removed from the chemical-specific database for evaluation of BMI via surface water, since daphnids are often highly sensitive to metals in surface water but are unlikely to be abundant in riverine environments. This same recommendation applies to evaluation of surface water-related risks for fish and zooplankton (i.e., limit toxicity data to each receptor group: fish data for fish, daphnid data for zooplankton, BMI data for BMI), where data quality and quantity allow.	
58	Page 269, Section 6.2.3.1, Table 6-16	Revise the table to confirm if total to dissolved conversion is based on EPA recommended CFs or on site specific data. Later text suggests EPA-recommended CFs, so please clarify on this table.	Revision is acceptable.
59	Page 270, Section 6.2.3.1, Table 6-16 (zinc)	Regarding the use of BLM for zinc, EPA will provide feedback on this topic under separate cover.	Acceptable.
60	Page 277, Section 6.2.3.2, second paragraph	490 mg/L (as $CaCO_3$) is an abnormally elevated average hardness. The text should provide a distribution or range of water hardness values. Hardness is a measure for freshwater. However, hardness data were collected for many locations that were actually estuarine. NJDEP classifies freshwater as ≤3.5 ppt salinity at mean high tide. Saline locations (>3.5ppt at mean high tide) should be compared to saline screening values and/or TRVs. Freshwater locations should be compared to freshwater screening values and/or TRVs on a per-sample basis, or on a per-reach basis to more appropriately utilize the hardness correction for toxicity screening of hardness-dependent metals. If no site-specific hardness data is available, use the default of 100 mg/L as $CaCO_3$. The National Recommended Water Quality Criteria	Revision is acceptable.

		(NRWQC) guidance recommends for hardness >400 mg/L: 1) calculate the criterion using a default water effect ratio (WER) of 1.0 and using a hardness of 400 mg/L in the hardness equation; or 2) calculate the criterion using a WER and the actual ambient hardness of the surface water in the equation. Revise the text, and revise the calculations for hardness and for hardness-dependent metals throughout the BERA.	
61	Page 277, Section 6.2.3.2, Chromium	Confirm that the text is accurate. CMC and CCC look like Cr +6 criteria, yet most Cr in surface water is likely to occur as Cr +3 (criteria are much higher for Cr +3, and those criteria are hardness-dependent).	Revision is acceptable.
62	Page 278, Section 6.2.3.2, Lead	Regarding the use of BLM for lead, EPA will provide feedback on this topic under separate cover.	Revision is acceptable.
63	Page 308, Section 6.2.6, last paragraph	The paragraph has a mixed discussion of cyanide and TCDD, and should be broken into separate paragraphs for each contaminant category.	Revision is acceptable.
64	Page 312, Section 6.3.3.1	Benthic invertebrate tissue TRVs should be revised, as appropriate, to address the attached TRV review spreadsheet, which was based on EPA's review of the studies CPG used to derive TRVs.	Partially acceptable. EPA and CPG went through a long process to develop a list of TRVs for use in the BERA. CPG submitted all of the citations from which their alternative TRVs were developed, and EPA reviewed the papers to verify the selected values. EPA, in turn, provided all of the citations CPG requested from which EPA's TRVs were developed. CPG commented on EPA's values, and EPA responded with all of the necessary technical information. After several months of conference calls, emails, and in-person meetings, an agreed-to list of TRVs was compiled including both CPG's and EPA's values. In this section of the Revision 2 draft report, CPG has included new TRV values for several chemicals. Some are acceptable, and some are not. See below and revise these TRVs in Tables 6-20 and 6-21. The Revision 2 BERA has included a new alternative NOAEL TRV for arsenic (0.064 mg/kg) which is 10-fold lower than the verified LOAEL (0.64 mg/kg). This new TRV is acceptable. The BERA includes a new alternative NOAEL TRV for cadmium (0.12 mg/kg) which is half of the verified LOAEL TRV (0.24 mg/kg). This is

			not acceptable. The NOAEL TRV should be a 10-fold reduction of the verified LOAEV TRV (0.024 mg/kg). The alternative NOAEL TRV for zinc was changed from 18 mg/kg to 8 mg/kg. This is acceptable. The alternative NOAEL TRV for Total PCBs was changed from no value to 400 µg/kg. This is unacceptable. If CPG is going to insert a new value, the verified LOAEL (520 µg/kg) should be divided by 10 to get a NOAEL of 52 µg/kg. The alternative NOAEL TRV (478 µg/kg) and LOAEL TRV (4,780 µg/kg) values for dieldrin were changed to 8 µg/kg and 80 µg/kg, respectively. This is acceptable. The alternative LOAEL for Total DDx was changed from 10 µg/kg to 110 µg/kg. This is not acceptable. The NOAEL TRV for Total DDx was changed from no value to 60 µg/kg. This is unacceptable. The verified LOAEL TRV (10 µg/kg) should be divided by 10 to derive the NOAEL TRV (1 µg/kg). Revise these tables, the text, any tables in which these TRVs were used for calculations, and all results and conclusions to make these changes.
65	Page 313, Section 6.3.3.1, first paragraph	The text states that "HQs greater than or equal to 1.0 based on NOAELs do not indicate whether an adverse effect can be expected. Therefore, LOAELs were considered appropriate for developing SSDs to determine the potential for an adverse effect." In accordance with EPA (1997), Section 7.3.1, the NOAEL represent the lower bound of risk and the LOAEL represents the upper bound of risk. Therefore, the statement is incorrect and both the NOAEL and the LOAEL must be used in the risk assessment.	Partially acceptable. See EPA Comment No. 64.

		The text further states that "the geometric mean of all chronic LOAELs for that endpoint was calculated to determine the final endpoint value. If LOAELs for multiple endpoints were available, the lowest value among the endpoints was selected." The NOAEL and LOAEL from the FFS should be used.	
66	Page 319, Table 6-23	The footnote "f" is used for the NOAEL value for Nickel; however, footnote "f" is "Mercury TRV based on Norway lobster and shore crab hepatopancreas tissue concentrations was selected for comparison to LPRSA blue crab hepatopancreas tissue." Mercury is not included on Table 6-23. An explanation of this footnote is required.	Revision is acceptable.
67	Pages 324-325, Figures 6-28 and 6-29	The text states (in Section 6.3.3.1) that the "model that best fit the underlying data distribution was selected by considering the fit statistics provided by @RISK, visual examination of the curve, and the final species LOAELs at the low end of the distribution;" however, visual examination of several of the curves (Figure 6-28 and Figure 6-29 as examples) shows that the curves do not fit the data, and a curve with a better fit would produce a LOAEL orders of magnitude lower. NJDEP did not have the ability to examine the @RISK software; however, the curves do not appear accurate. The curves do not appear to be properly fit. Further justification for the curve is required. The data should be recalculated. When there are few values (as with Figure 6-29) the lowest value should be utilized, instead of plotting a curve. Also include the @RISK program data requirements (how many sample points are required to fit a curve).	Revision is acceptable.
68	Page 324, Section 6.3.3.2, Dieldrin	The LOAEL and NOAEL for dieldrin were based on an acute study without applying an ACR. This results in a LOAEL and NOAEL three orders of magnitude higher	Revision is acceptable. See EPA Comment No. 64.

		than the LOAEL and NOAEL used in the FFS. The use of an acute study should be reexamined, and the implications of using the acute value versus the more appropriate chronic value should be discussed. The BERA should use chronic NOAEL and LOAEL values from the FFS document. The dieldrin section should be revised.	
69	Page 327, Section 6.3.3.2, Cadmium	In the cadmium section, the text refers to Figure 6-30; however, Figure 6-30 shows a relationship for arsenic. The correct citation should be Figure 6-31.	Revision is acceptable.
70	Page 335, Section 6.3.5	The text states that "All TRVs were selected from only one or two available toxicity studies;" however, this is an incorrect statement. For instance, 60 studies were used to generate the cadmium TRV, eight studies were used to generate the DDx TRV, and nine studies were used to generate the PCB TRV. Therefore, this statement should be corrected.	Revision is acceptable.
71	Page 335, Section 6.3.5.1	Page 336 is missing from the electronic version of the BERA.	Revision is acceptable.
72	Page 342	This page is missing from the electronic version of the BERA.	Revision is acceptable.
72a	Section 6.3.6	-no comment on 2016 draft-	The Revision 2 Draft BERA pdf has a portion of Section 6.3.6 truncated and missing between Tables 6-25 and 6-26, and the formatting between pages 340 and 352 cuts off portions of paragraphs. The Word version was not affected.
73	Page 350, Section 7.1.3.1	Fish tissue TRVs should be revised, as appropriate, to address the attached TRV review spreadsheet, which was based on EPA's review of the studies CPG used to derive TRVs.	Partially acceptable. EPA and CPG went through a long process to develop a list of TRVs for use in the BERA. CPG submitted all of the citations from which their alternative TRVs were developed, and EPA reviewed the papers to verify the selected values. EPA, in turn, provided all of the citations CPG requested from which EPA's TRVs were developed. CPG commented on EPA's values, and EPA responded with all of the necessary technical information. After several months of conference calls, emails, and in-person meetings, an agreed-to list of TRVs was compiled including both CPG's and

			EPA's values. However, in this section of the Revision 2 draft report, CPG has included several new values. Some are acceptable, and some are not. See below and revise the following TRVs in Tables 7-6 and 7-7. The Revision 2 BERA has included a new alternative NOAEL TRV for cadmium (0.13 mg/kg) which is 19% lower than the verified LOAEL (0.16 mg/kg). This is unacceptable. The NOAEL TRV value should be 1/10th of the verified LOAEL TRV (0.016 mg/kg). The BERA includes a new alternative NOAEL TRV for methylmercury (230 µg/kg) which is 35% lower than the verified LOAEL TRV (350 µg/kg). This is unacceptable. This NOAEL TRV (35 µg/kg) should also be a 10-fold reduction of the verified LOAEL TRV. The alternative NOAEL TRV for Total PCBs was changed from no value to 3,200 µg/kg. This is unacceptable. If CPG is going to insert a new value, the verified LOAEL (3,800 µg/kg) should be divided by 10 to get a NOAEL of 380 µg/kg. The alternative NOAEL TRV for PCB TEQ was changed from no value to 72 µg/kg. This is unacceptable. That value is higher than the verified LOAEL values of 23 µg/kg and 120 µg/kg. If CPG is going to insert a new value, the verified LOAEL TRV (23 µg/kg) should be divided by 10 to get a NOAEL TRV of 2.3 µg/kg. The alternative NOAEL TRV for Total DDx was changed from no value to 52 µg/kg, which is 1/10th the verified LOAEL value (520 µg/kg). This is acceptable. Revise these tables, the text, any tables in which these TRVs were used for calculations, and all results and conclusions to make these changes.
74	Page 359, Total PCBs	a. The text states that for total PCBs, LOAELs "ranging from 0.63 to 92 mg/kg ww" were selected; however, this does not match the range shown in	Partially acceptable. See EPA comment No. 73.

		Figure 7-2, even when corrected for the difference in units. Either the text or the figure needs to be corrected. b. In addition, the SSD of 5,600 µg/kg ww taken from Figure 7-2 is an order of magnitude higher than the lower end of the range; however, the figure shows the SSD intersecting the lowest LOAEL value. Clarification is required.	
75	Pages 360-361, Figures 7-3 and 7-4	Visual examination of several of the curves (Figure 7-3 and Figure 7-4 as examples) shows that the curves do not appear to fit the data, and a curve with a better fit would produce a LOAEL an order of magnitude lower. See earlier comments on figures 6-28 and 6-29.	Revision is acceptable.
76	Page 375, Section 7.1.4.2	This section is out of order (after 7.1.4.3) in the electronic version of the BERA.	Revision is acceptable.
77	Page 379, Section 7.1.4.4, second paragraph	The text states that "background maximum concentrations were calculated using banded killifish, smallmouth bass, and channel catfish data for comparison to LPRSA EPCs for mummichog, largemouth bass, and white catfish, respectively." Given that the majority of the EPCs were based on the UCL, then the UCL of the background data must be used for comparison to those EPCs in order to compare like statistics in accordance with NJDEP (2015), Section 5.3.4.	Revision is acceptable.
78	Page 391, Section 7.2.2.3	The text states that "Site-specific data indicate that benthic invertebrates in the LPRSA are most likely to inhabit the 0- to 2-cm depth horizon, which may have lower chemical concentrations, and thus result in lower tissue concentrations than those from the bioaccumulation study. This is discussed in the CSM (Section 3.3). The available tissue data do not include other prey items that may be important components of the fish diets, such as amphipods, algae, zooplankton, or detritus; therefore, the representativeness of the revised draft BERA dietary	Revision is acceptable.

		estimates for fish (based on available prey tissue data) of actual LPRSA fish diets is uncertain." Based on the 2-cm dispute resolution, EPA concluded that that the use of the 0-2 cm zone for modelling was inappropriate. This statement only confounds the issue, which was previously resolved. This statement should be removed from this section and placed into the uncertainty section. All of the text between Table 7-20 and Table 7-21 should be removed from this section and placed into the uncertainty section.	
79	Page 400, Section 7.2.3.1	Fish dietary TRVs should be revised, as appropriate, to address the attached TRV review spreadsheet, which was based on EPA's review of the studies CPG used to derive TRVs.	Unacceptable. EPA and CPG went through a long process to develop a list of TRVs for use in the BERA. CPG submitted all of the citations from which their alternative TRVs were developed, and EPA reviewed the papers to verify the selected values. EPA, in turn, provided all of the citations CPG requested from which EPA's TRVs were developed. CPG commented on EPA's values, and EPA responded with all of the necessary technical information. After several months of conference calls, emails, and in-person meetings, an agreed-to list of TRVs was compiled including both CPG's and EPA's values. In Section 7.2.3.1 of the Revision 2 draft report CPG has included two new values. Both new values are not acceptable. The following TRVs from Table 7-22 must be revised: The Revision 2 BERA has included a new alternative NOAEL TRV for chromium (0.92 mg/kg) which is nearly 5 times higher than the verified NOAEL (0.19 mg/kg). This is unacceptable. The Revision 2 BERA has included a new alternative NOAEL TRV for vanadium (0.038 mg/kg) which is two times higher than the verified NOAEL (0.019 mg/kg). This is unacceptable. Revise Table 7-22, the text, any tables in which these TRVs were used for calculations, and all results and conclusions to make these changes.

80	Page 410, Section 7.3.2, second paragraph	The second paragraph should be removed and placed into the uncertainty section.	Revision is acceptable.
81	Page 412, Table 7-27	Reach-specific data for hardness (freshwater area) should be included, since metals toxicity is hardness dependent in some cases.	Revision is acceptable, now listed as Table 7-28.
82	Page 413, Section 7.3.3	The text states that "Some of the selected surface water TRVs may be overly protective of fish, because the TRVs are based on SSDs largely driven by invertebrate species, as described in Table 7-28." This statement should be removed and placed into the uncertainty section.	Revision is acceptable.
83	Page 416, Table 7-28 (lead and zinc)	See previous comments on applicability and acceptance of BLMs for metals other than copper	Revision is acceptable.
84	Page 425, Table 7-29	Confirm that acute and chronic HQs for copper are equal.	Revision is acceptable.
85	Page 433, Section 7.4.2	In addition to the Niimi (1983) paper, the Russell et al. (1999; Env. Sci. Tech. 33:416-420) paper, which also supports a 1:1 ratio of internal concentration to egg concentration, should be added as it expands on the Niimi paper, is more current, and has a larger dataset.	Revision is acceptable.
86	Page 436, Section 7.4.3.1	Fish egg tissue TRVs should be revised, as appropriate, to address the attached TRV review spreadsheet, which was based on EPA's review of the studies CPG used to derive TRVs.	Unacceptable. EPA and CPG went through a long process to develop a list of TRVs for use in the BERA. CPG submitted all of the citations from which their alternative TRVs were developed, and EPA reviewed the papers to verify the selected values. EPA, in turn, submitted all of the citations CPG requested from which EPA's TRVs were developed. CPG critiqued EPA's values, and EPA responded with all of the necessary technical information. After several months of conference calls, emails, and in-person meetings, an agreed-to list of TRVs was compiled including both CPG's and EPA's values. For CPG to include new values at this stage is not acceptable. The following TRVs from Table 7-34 must be revised:

			The Revision 2 BERA has included a new alternative NOAEL TRV for Total PCBs (50.4 ug/kg) which is nearly two times higher than the verified NOAEL (25.8 ug/kg). This is unacceptable. Revise these tables, the text, any tables in which these TRVs were used for calculations, and all results and conclusions to make these changes.
87	Page 446, Section 7.5, first paragraph, last sentence	The following statement should be removed: "Although there is uncertainty in comparing data from the LPRSA to data from other studies, these egg weights and counts do not indicate adverse reproductive effects that could affect the mummichog population". At most, this indicates that egg weights and counts might be within ranges of other studies; however, it provides no indication regarding potential reproductive effects associated with TEQs such as reduced hatching success or embryo mortality. Egg count data pertain to fecundity, not fertility. Clarifying text should be added to specify that assessments of fertility, and overall reproductive success, cannot be made from egg count and egg weights alone. This information has no bearing on the absence of mummichog population effects.	The revision is acceptable.
88	Page 460	Although these endpoints and the studies underlying much of the effects data are based on individual organisms, it is common and accepted practice to assume that significant risks to receptors at this level can be used to assume population level effects. Clearly, survival and reproduction of individuals can affect populations and communities. Test should be revised to reflect this.	The revision is acceptable (now page 491, last paragraph).
89	Page 466, Section 8.1.2.1	In Equation 8-1, the Food Ingestion Rate (FIR), and the prey tissue Exposure Point Concentration (EPC) are both appropriately expressed on a wet weight basis. However, in Equation 8-2, the EPCprey is expressed as dry weight. Equation 8-2 should be corrected, since	Revision is acceptable.

		the expressions of FIR and EPCprey must be consistent. Confirm that when using EPC prey as dry weight, that corresponding ingestion rate is also dry weight (or wet weight to wet weight). The prey and ingesting rates must be in the same units.	
90	Page 468, Section 8.1.2.3	Regarding prey composition dietary scenarios, the "first scenario" fish size class for the great blue heron and kingfisher stated on page 469 appear to be reversed from the Table 8-4 presentation. For example, for the great blue heron, text states that the first scenario is fish <9 cm, while the table indicates the first scenario to be <13 cm. Table 8-4 is also missing an explanation for footnotes b and c. Please correct as appropriate. Text introducing uncertainty related to worm exposure to 0-2 cm vs 0-15 cm sediment depths should be removed from this section.	Revision is acceptable.
91	Page 483, Section 8.1.3.1	Bird dietary TRVs should be revised, as appropriate, to address the attached TRV review spreadsheet, which was based on EPA's review of the studies CPG used to derive TRVs.	Unacceptable. EPA and CPG went through a long process to develop a list of TRVs for use in the BERA. CPG submitted all of the citations from which their TRVs were developed, and EPA reviewed the papers to verify the selected values. EPA, in turn, provided all of the citations CPG requested from which EPA's TRVs were developed. CPG commented on EPA's values, and EPA responded with all of the necessary technical information. After several months of conference calls, emails, and in-person meetings, an agreed-to list of TRVs was compiled including both CPG's and EPA's values. One new TRV value for has been included in Table 8-11 of this report. They are not acceptable. See below and the following TRVs from Table 8-11 must be revised: The NOAEL TRV for methylmercury was changed from no value to 50 µg/kg, which is more than half of the verified LOAEL value (96 µg/kg). This is unacceptable. The alternative NOAEL TRV should be 9.6 µg/kg, or 1/10th the verified LOAEL TRV.

			Additionally, the EPA TRVs (listed as TRV-B) for nickel (NOAEL=1.38 mg/kg, LOAEL=56.3 mg/kg); selenium (NOAEL=0.23 mg/kg, LOAEL=0.93 mg/kg); and zinc (NOAEL=17.2 mg/kg, LOAEL=172 mg/kg) are not listed in Table 8-11. Revise to include these EPA TRVs. Revise Table 8-11, the text, any tables in which these TRVs were used for calculations, and all results and conclusions to make these changes.
92	Page 491, Section 8.1.3.2, Methyl Mercury	The LOAEL and NOAEL values for Mercury from Louis Berger et al., 2014 stated in the text are reversed in the first sentence, and should be corrected.	Revision is acceptable.
93	Page 533, Section 8.1.4.3, last sentence	Despite higher lipid normalized maximum concentrations in fish from reference areas, it should be noted that higher lipid contents in fish from reference area may indicate better fish condition as compared to LPRSA fish, which had reduced lipid content relative to reference area.	Revision is acceptable.
94	Page 545-546, Table 8-22	Table 8-22 is labeled “Summary of Prey EPCs for Bird Species”, but does not present EPCs. The table should be titled “Summary of Prey Composition for Bird Species”.	Revision is acceptable (now Table 8-23).
95	Page 561, Section 8.2.3.1	Bird egg tissue TRVs should be revised, as appropriate, to address the attached TRV review spreadsheet, which was based on EPA’s review of the studies CPG used to derive TRVs.	Unacceptable. EPA and CPG went through a long process to develop a list of TRVs for use in the BERA. CPG submitted all of the citations from which their TRVs were developed, and EPA reviewed the papers to verify the selected values. EPA, in turn, provided all of the citations CPG requested from which EPA’s TRVs were developed. CPG commented on EPA’s values, and EPA responded with all of the necessary technical information. After several months of conference calls, emails, and in-person meetings, an agreed-to list of TRVs was compiled including both CPG’s and EPA’s values. In Table 8-27 of this report, CPG has included few new values which are not acceptable. The following TRVs from Table 8-27 must be revised: The alternative NOAEL TRVs for PCDD/PCDF TEQ, Total TEQ, and PCB TEQ were changed from no value to 100 ng/kg, which is nearly half

			of the verified LOAEL value (250 ng/kg). This is unacceptable. The alternative NOAEL TRVs should be 25 ng/kg, or 1/10th the verified LOAEL TRVs. The alternative NOAEL TRV for Total DDx was changed from no value to 3,900 µg/kg, which is only 5% lower than the verified LOAEL value (4,100 µg/kg). This is unacceptable. The alternative NOAEL TRV should be 410 ng/kg, or 1/10th the verified LOAEL TRV. Revise Table 8-27, the text, any tables in which these TRVs were used for calculations, and all results and conclusions to make these changes.
96	Page 565, top of page	Latin names of species should be italicized.	Revision is acceptable. However, Latin names of species are not italicized in Figure 8-7. Revise Figure 8-7.
97	Page 589	See previous comment regarding interpretation of organism level risks vs. population level risks.	Revision is acceptable.
98	Page 613, Section 9.1.3.1	Mammal dietary TRVs should be revised, as appropriate, to address the attached TRV review spreadsheet, which was based on EPA's review of the studies CPG used to derive TRVs.	Unacceptable. EPA and CPG went through a long process to develop a list of TRVs for use in the BERA. CPG submitted all of the citations from which their TRVs were developed, and EPA reviewed the papers to verify the selected values. EPA, in turn, provided all of the citations CPG requested from which EPA's TRVs were developed. CPG commented on EPA's values, and EPA responded with all of the necessary technical information. After several months of conference calls, emails, and in-person meetings, an agreed-to list of TRVs was compiled including both CPG's and EPA's values. The following TRVs are not listed in Table 9-12. Revise Table 9-12 to include these EPA TRVs. The EPA TRVs (listed as TRV-B) for arsenic (NOAEL=0.32 mg/kg, LOAEL=4.7 mg/kg); cadmium (NOAEL=0.06 mg/kg, LOAEL=2.64 mg/kg); nickel (NOAEL=0.133 mg/kg, LOAEL=31.6 mg/kg), selenium (NOAEL=0.05 mg/kg, LOAEL=1.21 mg/kg), and zinc (NOAEL=9.6 mg/kg, LOAEL=411 mg/kg) are not listed in Table 9-12. Revise Table 9-12, the text, any tables in which these TRVs were used for calculations, and all results and conclusions to make these changes.

98a	Section 9.1.3.1	-no comment on 2016 document-	The mammal dietary NOAEL TRV for nickel is noted in the text as 20 mg/kg bw/d, but in Table 9-12 the NOAEL TRV is listed as 40 mg/kg bw/d. Revise appropriately – the correct value is 40 mg/kg bw/d.
99	Page 653, Section 9.1.4.2, Table 9-18	The text above the table refers to Appendix H, which does not indicate how populations were derived. The table lists percentages of population. Insert a discussion of how the population percentages were derived.	Revision is acceptable.
100	Appendix A, SLERA, General	There was more inclusion of carp in the text and tables, as requested in EPA's first round of BERA comments. However, in Table 3.3, carp should also be evaluated based on their dietary consumption as a benthic omnivore.	Revision is acceptable.
101	Appendix A, SLERA, General	Within the context of risk evaluation, the differentiation between focal and non-focal species is unclear. Classifying species as non-focal seems to imply their potential to be at risk is not as important (e.g., consider risks to carp, white sucker, white catfish). While the risk assessment should keep protection of species of concern (e.g., threatened, endangered, listed species) as a separate issue, the rest of the receptors (and potential receptors) associated with a site should be considered equally important whether they are native/non-native, or focal/non-focal.	Revision is acceptable.
101a	Appendix A, SLERA	-no comment on 2016 draft-	On Tables 3-10 through 3-17; the CPG-related TRV tables have a column titled "rationale", but the EPA-related TRV tables have a column titled, "Notes/Key uncertainties". As discussed numerous times in emails, calls, and meetings, calling the EPA's TRVs inappropriate or less appropriate than those derived by CPG is not acceptable. CPG will choose one of the following options: 1) delete the "rationale" and "Notes/Key uncertainties" columns; 2) make the same uncertainty comments for CPG's TRVs; or 3) EPA will re-write the document.

101b	Appendix A, SLERA	-no comment on 2016 draft-	On Table 3-17, in the "Notes/Key uncertainties" column for PCDD/PCDF TEQ, there is a discussion indicating that including chicken data is not appropriate. Delete all reference to chicken data as being too sensitive. As noted in EPA's 12/22/15 BERA comments, comment ID 125 (the documents that were attached to the 12/22/15 comments are not attached to these comments): "Relevant agencies and contractor staff evaluated the sensitivity of several bird species to PCB exposures, based on genetic sequences related to AH receptor (i.e., evaluation of dioxin-like effects) for the Kalamazoo River NPL site in western Michigan. This evaluation built upon existing toxicity data and ongoing studies conducted by Sean Kennedy (numerous papers), National Wildlife Research Centre, Environment Canada, Ottawa, ON, Canada. For the Kalamazoo River NPL site, it was determined that 142 bird species have been recorded to occur onsite or have high potential to occur within the NPL site boundaries. Of these, only 7 had been sequenced at the time the Kalamazoo site was first investigated. The attached Word file (Confidence Interval for Number of Sensitive Species.docx) presents a summary of the statistical evaluation of the likelihood that domestic chickens are actually the most sensitive avian species of all those that could occur within the Kalamazoo NPL site. As of 2014, several more species (75) had been sequenced. These additional data (see attached, Avian AHR.xlsx) reveal that bird species as sensitive or nearly as sensitive to PCBs (based on genetic sequencing) as domestic chicken (Group 1, highly sensitive) include red jungle fowl, ruby-throated hummingbird, European starling, and gray catbird – only one of which can be considered closely related to domestic chicken. Approximately half (38) of the remaining bird species were assigned to Group 2 (moderately sensitive), while 32 taxa were assigned to Group 3 (least sensitive).

<table>
<tr><td></td><td></td><td></td><td>These findings indicate that highly sensitive avian species, again based ONLY on genetic sequencing and NOT on experimentally derived toxicity data, comprise about 7% of birds sequenced. Half (50%) are considered moderately sensitive, and about 40% are considered to have low sensitivity to dioxin-like PCBs.

Finally, it is important to note that dioxin-like effects linked to avian genetics and AHR do not address all the other adverse effects not associated with AHR. See Table 3 below, reproduced from DeVito and Henry, 2003.

Table 3. Toxicity Pathways Documented for Non-Dioxin-Like PCBs
<table>
<tr><th></th><th colspan="4">Organism Class</th></tr>
<tr><th>Toxicity Pathway</th><th>Invertebrate</th><th>Fish</th><th>Birds</th><th>Mammals</th></tr>
<tr><td>Narcosis</td><td>X</td><td>X</td><td>X</td><td>X</td></tr>
<tr><td>Liver Effects</td><td>N/A</td><td>?</td><td>?</td><td>X</td></tr>
<tr><td>Neurochemical / behavioral</td><td>?</td><td>?</td><td>?</td><td>X</td></tr>
<tr><td>Endocrine / Neuroendocrine</td><td>?</td><td></td><td>?</td><td>X</td></tr>
<tr><td>Immunological</td><td>X</td><td>?</td><td>?</td><td>X</td></tr>
</table>

DeVito and Henry. 2000. NON-DIOXIN-LIKE PCBs: EFFECTS AND CONSIDERATION IN ECOLOGICAL RISK ASSESSMENT. USEPA. Experimental Toxicology Division. National Health and Environmental Effects Research Laboratory. Office of Research and Development "</td></tr>
<tr><td>102</td><td>Appendix A, SLERA, Page 14</td><td>Sediment depths and intervals used should be specified here.</td><td>Revision is acceptable.</td></tr>
<tr><td>103</td><td>Appendix A, SLERA, Page 18, Section 2.1.2</td><td>The text states that no surface water samples were collected above RM10.2, but the bullets state that surface water samples from above Mile 4 to below Mile 13 were compared to TSVs. The text should be clarified to indicate where samples were collected and how the results were then incorporated into dietary dose estimation (Section 3.2.2).</td><td>Revision is acceptable.</td></tr>
</table>

		State the rationale for using sediment salinity zones for surface water. The lowest of the two TSVs (freshwater vs estuarine) should be used. Further, the surface water statistics in App A, Attachment 1, show a large range of salinities. The statistics do not indicate whether samples were collected at low/high tide, so it is not clear which samples are included in the statistical means (e.g., >RM4 range of salinity is 2.5-20ppt, and <RM13 range is 8.5-24.9ppt). The text should be clear regarding which samples were considered salt and which were fresh.	
104	Appendix A, SLERA, Page 18, Table 2-2, and Footnote G	Clarification is needed in the text regarding how the whole body calculations were performed (e.g., on a per-animal basis or on a composite basis) for each species. Also, the eel and fish fillet data are reported to be evaluated in the HHRA, but are the rest of the samples analyzed in the SLERA? Tissue and surface water/sediment data should be provided.	Revision is acceptable.
105	Appendix A, SLERA, Page 21, Section 3	Per comment 172 from original EPA 5/1/15 RTC matrix, the detection limits for non-detects needs to also be compared to the TSVs. If the detection limit is greater than the TSV, then the contaminant should be retained. Further, TSVs should be able to be determined for all contaminants. Potential sources include those not listed in the SLERA, from the primary literature, etc.	Revision is acceptable.
106	Appendix A, SLERA, Page 23, Diet	Dietary COIs for fish were limited to metals and PAHs. See comment 177 from original 5/1/15 RTC document. All contaminants should be used for dose estimates for corresponding fish feeding guilds and screened against conservative NOAEL-based TRVs.	Revision is acceptable.
107	Appendix A, SLERA, Page 30, Table 3-2	It seems that the most conservative values were used (lowest body weights, highest ingestion rates), but the column title wasn't updated. Verify that conservative	Revision is acceptable.

		values were in fact used, and then update column title.	
108	Appendix A, SLERA, Page 33, Table 3-3	Carp and suckers were not included with the benthic omnivorous fish. The SLERA needs to be revised to include all potential receptors.	Revision is acceptable.
109	Appendix A, SLERA, Page 34, Section 3.2.3.1	Additional references and rationale provided in EPA's 5/1/15 RTC matrix comment 183 were not incorporated. The CPG's response to this comment was that this approach was not carried forward into the BERA, and those results would not differ. However, incorrectly estimated values in the SLERA could affect what gets more definitively assessed in the BERA. The references should be included in the SLERA.	Revision is acceptable.
110	Appendix A, SLERA, Page 63, Tables 3-10, 3-11, 3-12	Most of the survival endpoints are acute data (lethal), as opposed to chronic (sub-lethal). If CPG can't find appropriate chronic data, an acute-to-chronic conversion factor (e.g., 10) should be used. That may significantly change several of these values. The SLERA should be revised to include appropriate sub-lethal data. The text should include detail about how the values were derived (which studies were used and why). While the full explanations are in attachments to the appendix, the rationale needs to be discussed in the text.	Revision is acceptable.
111	Appendix A, SLERA, Page 97, Dietary Dose Derivation	Need to verify in the text that all fish sizes were included as prey, not just small forage fish (<30 cm).	Revision is acceptable.
112	Appendix A, SLERA, Page 153, Section 6	Comment 206 from the 5/1/15 RTC matrix states that dioxin was not listed for benthic invertebrate tissue or fish dietary tissue. In the updated Attachment A2, dioxin is included in benthic invertebrate tissue, but is listed as "Dioxin TEQ-Fish" and "Total TEQ-Fish." It is unclear what that means, and dioxins are not included	Revision is acceptable.

		in the table for fish dietary tissue in Attachment A2. Clarify the section.	
113	Appendix A, SLERA, Attachment A2	EPA has revised the selenium threshold for freshwater lotic systems to 3.1 µg/L*. However, according to the methodology described in the BERA, the lowest value of 1 µg/L (Canadian Council of Ministers of the Environment) should be selected for the selenium TSV. If rationale exists for selecting 5 µg/L for selenium (Appendix A, Attachment A2, Table A2-4 “SLERA results for aquatic organisms and freshwater surface water”) then that justification should be provided in the text. This recommendation applies for all contaminants of interest for which an exception to the methodology of selecting the lowest value has been made. *https://www.epa.gov/wqc/aquatic-life-criterion-selenium-documents	Revision is acceptable.
114	Appendix A, SLERA, Attachment A2	Page 20 of the SLERA states that “HQs, presented in Attachment A2, are rounded to two significant figures.” This does not appear to be the case. Attachment A2 (specifically A2-9, A2-11, and A2-12) should be subjected to a quality assurance/quality control review.	Revision is acceptable.
115	Appendix A, Attachments A1 and A2	There are discrepancies between values reported in Appendix A, Attachment A1 and Appendix A, Attachment A2. For example, in Attachment A1, a maximum concentration of 18,900 mg/kg is reported for aluminum in sediment from all site areas, yet aluminum is not included in the screening tables for sediments (Tables A2-1 and A2-2). Similarly, iron and thallium are not in the sediment screening tables in Attachment A2. These tables should be subject to a QA/QC review and errors/omissions should be corrected.	Revision is acceptable.

116	Appendix B, Benthic Data Calculation, General Comment	Appendix B is mentioned three times in the Revised Draft BERA: in the table of Contents; in a list of appendices at the end of Section 1; and in one sentence on page 248 that states, "The results of the medium impact evaluation (based on WOE results) are provided in Appendix B." The BERA gives no explanation or discussion of the 46 tables of statistical calculations in Appendix B, or where the information came from, or what it means. There was also no explanation/discussion given in Appendix B; it was simply a set of tables. It was left to the reviewer to intuit and interpret this large set of data that CPG called "weight of evidence" (WOE) results. The BERA states that the results of the WOE in Appendix B are summarized in Tables 6-8 and 6-9 (which are both reproduced from tables in Appendix B). However, the two tables list values that are not adequately explained in the text. At EPA's request, the CPG submitted a revised cover section "Annotated List of Tables" for Appendix B on 12/21/16, with more detailed descriptions of what each of the data tables contain and where the data came from. The data tables themselves were not revised with the cover section. While the revised cover section does a better job of describing the tables and data manipulations, there is no actual discussion of what any of it means or how it relates to the derivation of the "medium impact evaluation" listed in BERA Tables 6-9 and 6-9. It is obvious from Appendix B that a significant amount of work was performed to derive the values used in the BERA. However, the BERA does not adequately	Revision is acceptable.

		discuss what was done, why it was done, and what it means with regard to ecological risk. Add a section to the BERA that fully explains Appendix B; which source data tables were used (and include them in the BERA), what calculations were performed, and how the conclusions were derived. Add notes to each table explaining what data is included, where it came from and the calculations/equations/assumptions utilized (without calculations/equations/assumptions, EPA cannot recreate any of CPG's findings). The BERA and all appendices and supporting materials must be transparent, objective, adequately described, and sufficiently supported by the available data.	
117	Appendix B, Annotated List of Tables	Table descriptions: There are at least five mentions of "direction from USEPA Region 2", EPA provided guidance and not direction for the performance of the BERA. Delete the phrases.	Revision is acceptable.
118	Appendix B, Tables	Tables B4: In EPA's 5/1/2015 comments on the initial draft of the BERA (Comment ID No. 216), EPA requested that CPG include the sediment toxicity test growth endpoints in the SRC analyses (i.e., *Hyalella azteca* and *Chironomus dilutus* growth). CPG responded on 9/10/2015 that inclusion of dry weight would be redundant, because biomass was already included. EPA's 12/22/2015 response stated that EPA would like to see the growth data, even if it is redundant. The growth data was not included in the Revised Draft BERA. This is unacceptable. CPG will include the growth data, and all appropriate statistical analyses and interpretation before the BERA can be finalized.	Acceptable. The growth (dry weight) data were included in the Table B-1 spreadsheets. Because the data are included in the tables (even though not included in the statistical analyses as requested by EPA), and wouldn't likely significantly impact the overall results, the revision is acceptable.

119	Appendix C – BERA EPC Values – General Comment	Revise Appendix C to include a narrative section to explain what data (e.g., fish species) were included, the location of the data points, and the calculations/equations/assumptions utilized. The BERA and all appendices and supporting materials must be transparent, objective, adequately described, and sufficiently supported by the available data. EPC Key: LOE requiring UCLs: Sediment should be added to surface water under benthic invertebrate; egg tissue residue (modeled) should be added under spotted sandpiper; common carp should be added to the fish rows; and dietary dose should be added under white sucker. Benthic Tissue LOE – Tissue EPCs: For the mussels in the Benthic Tissue LOE, several compounds are listed as "need UCL". If a UCL cannot be calculated, the maximum detected value should be used for mussels.	Revision is acceptable.
119a	Appendix D – Surface Water TRVs	-no comment on 2016 draft-	On page 5, after the bullets, there is a discussion of the use of the "eight family" rule to derive SSD values. However, when sufficient data were not available, "a simple rule of a minimum of five species was required to develop an acute or chronic SSD for this evaluation." There was no explanation of how a five-species SSD would be derived. Additionally, the text needs to state that the five family derivations are more uncertain than the eight family derivations. Add text to describe how the five family SSD were derived. Also add the following text after that discussion: "The use of five families rather than eight families in the derivation of SSD values is a potentially significant source of uncertainty. It cannot be known whether the uncertainty would make the SSD values more conservative of less conservative."

120	Appendix D – Surface Water TRVs	Section 2.1.1 Cadmium: The second sentence says “chromium” instead of “cadmium”, and should be corrected. And the final sentence in this section says that both the freshwater and marine TSVs were adjusted to a hardness of 50 mg/L CaCO3. EPA’s default hardness value (in the absence of site-specific hardness) is 100 mg/L. Cadmium is a hardness-dependent metal, but hardness is not an issue in saltwater. If site-specific hardness data are available, they should be used, if not, the freshwater hardness value should be adjusted to 100 mg/L CaCO3, and if the marine value was adjusted for hardness, the value must be revised and saline water TSVs must be used.	Revision is acceptable.
121	Appendix D – Surface Water TRVs	Section 2.1.1.1 Freshwater: The first sentence says “zinc” instead of cadmium, and should be corrected. Additionally, the Draft 2015 AWQC was finalized in 2016. The freshwater CMC should be revised to 1.8 ug/L and the CCC should be revised to 0.72 ug/L. The final calculated TRVs should be recalculated.	Revision is acceptable.
122	Appendix D – Surface Water TRVs	Section 2.1.2.2 Saltwater: This section should be numbered 2.1.1.2. This section also references “zinc” instead of “cadmium”, and should be corrected. Additionally, the Draft 2015 AWQC was finalized in 2016. The saltwater CMC should be revised to 33 ug/L and the CCC should be revised to 7.9 ug/L. The final calculated TRVs should be recalculated.	Revision is acceptable.
123	Appendix D – Surface Water TRVs	General typographical errors: The section numbering is not sequential (e.g., 2.1.4 to 2.1.6 to 2.1.3.1). There appears to be a number of errors in the text; the section on cadmium mentions chromium and zinc, the section on chromium mentions cadmium, the section on mercury mentions cadmium, etc. While reviewing the text for this appendix, it was difficult to know whether or not the sections had been switched around. The entire appendix should be proof-read	Revision is acceptable.

		(including the CMC and CCC values that are listed for each COPEC), and the necessary corrections made.	
123a	Appendix E – Toxicity Reference Values	-no comment on 2016 draft-	On page 4, footnote, the first sentence does not appear to be consistent with CPG's past comments on TRV derivation. The footnote says, "Effects on cardiac or brain development, or other effects related to abnormal development, were included in the reproduction endpoint." CPG has previously said that developmental effects were not included in the reproduction endpoint. If the footnote is correct, no action is required. If the footnote is not correct, make the necessary revision.
124	Appendix E – Toxicity Reference Values	Sections 5.1.1.6 Nickel and 5.1.1.7 Selenium: It appears that the text for nickel (mammal dietary) is incorrect. The NOAEL and LOAEL values are the same as for selenium (0.05 and 1.21 mg/kg bw/day), as opposed to 0.133 mg/kg bw/day and 31.6 mg/kg bw/day listed in the tables. The error should be corrected.	Revision is partially acceptable. See EPA's TRV comments above.
125	Appendix E – Toxicity Reference Values	Toxicity Reference Value (TRV) acceptability criteria are included in this section, but are limited to studies that "directly measure survival, growth, or reproduction." Each section should have text describing the value chosen as the alternate TRV, the FFS-TRV, and then any uncertainty for each value that was selected. In addition, a table showing the studies used for the FFS-TRVs should be included. Finally, any text in this section should specify that the "requirements" for TRV study selection is for the alternative TRVs. a. As directed in the Jan. 13, 2016 conference call summary, comment 89, studies where these endpoints were not directly measured should not be excluded on this basis alone, but should be evaluated for their potential impacts at the population level. Adverse effects can include additional endpoints, such as hepatotoxicity or	Revision is partially acceptable. See EPA's TRV comments above.

		cardiac development, which may not be directly measured by survival, growth, and reproduction, but can have a major impact on these endpoints. b. References deemed by CPG to be “unacceptable” are not included in Appendix E Attachment E1. These references have been recommended by EPA and were used in the Lower Passaic River, Lower Eight-Mile Focused Feasibility Study and should be included in this attachment. Appendix E should also include the TRV information included in the attached TRV Review Spreadsheet.	
125a	Appendix F – Toxicity Profiles	-no comment on 2016 draft-	On page 9, Section 3.4, the first sentence must be revised to drop the text saying that the paper is inappropriate for TRV derivation, and simply state, “The toxic effects of 2,3,7,8-TCDD exposure on the Eastern oyster have been well studied by Wintermyer and Cooper (2003).”
126	Appendix H – Sensitivity Analysis for Mink and River Otter – General Comment	The sensitivity analysis was used to justify the HQs derived for mink and otters in the BERA. The field metabolic rate (FMR) for mink ranged from 120 to 258 kcal/kg bw/day from three studies, but CPG selected a 10th percentile value of 140 kcal rather than the 90th percentile value of 218 kcal/kg bw/day (yielding a significantly lower food ingestion rate for mink), or the free-living adult mink value from EPA’s Wildlife Exposures Handbook (236 to 258 kcal/kg bw/day). For the otter, CPG selected a 50th percentile value of 178 kcal/kg bw/day. The calculated FMR values need to be better explained, and the selected values need to be supported. Revise the text to clarify.	Revision is acceptable.
127	Appendix H – Sensitivity Analysis for Mink and River	Appendix H must include which source data tables were used (and include them in the BERA), what calculations were performed, and how the conclusions were derived. Add notes to each table explaining	Revision is acceptable.

	Otter – General Comment	what data is included, where it came from and the calculations/equations/assumptions utilized. The BERA and all appendices and supporting materials must be transparent, objective, adequately described, and sufficiently supported by the available data.	
128	Appendix H – Sensitivity Analysis for Mink and River Otter	Table 2-5: The sum total of mink dietary fractions only adds up to be 84.5%. It should add up to 100% of the mink's diet. Recalculate and revise, also ensure that the exposure modeling was performed with 100% of the proposed diet.	Revision is acceptable.
129	Appendix I – Mink Habitat Analysis	For BERA purposes, the mink is a surrogate for all species of aquatic feeding mammals. The exposure model is run using mink-specific body weight, ingestion rates, etc. However, the fact that there may not be prime mink habitat near the site is not a reason to state that there is no risk to aquatic-feeding mammals. Mammals and birds adapt to urban/suburban/commercial/industrial areas. While the EPA's Wildlife Exposures Handbook says mink prefer brushy or wooded cover adjacent to the water, that does not mean mink won't be found in the developed area surrounding the Passaic River. The habitat analysis is biased, and should not be used to lessen the potential for mink (or any other aquatic-feeding mammal) to be exposed to site-related contaminants. Revise the text to remove the inference that simply because there is no prime mink habitat there is no risk to aquatic-feeding mammals.	Acceptable.
130	Appendix J – Derivation of Background	The text states "within the BERA, it is necessary to distinguish impacts on biota caused by exposure to CERCLA hazardous substances from impacts caused by exposure to other stressors, including physical	Acceptable.

	Concentrations, Section 1	stressors." In accordance with EPA (1997), Section 1-8 and Highlight 1-4, "the baseline risk assessment addresses risks from hazardous substances released to the environment, not risks from physical alterations of the environment." Revise the text.	
130a	Appendix J – Figure 4-4	No comment on 2016 BERA	Figure 4-4 is titled, "Cumulative frequency of LPRSA and background 2,3,7,8-TCDD sediment concentrations". However, there is no LPRSA data included in the figure. Revise to include LPRSA data.
131	Appendix L – Background and Reference Area Data, Attachment L3	Many of the figures are missing data from one or more of the background or reference locations. An explanation of the reason these data are not included should be provided, perhaps as a footnote to each figure.	Revision is acceptable.
132	Appendix O	General comment: The TRVs derived for aquatic plants were derived from studies using an "uncertainty factor of 2". Revise the text to include a discussion, citation, and a justification for the uncertainty factor.	Revision is acceptable.
133	Appendix P, Section 2 Benthic Invertebrate Community Line of Evidence	When performing statistical analyses such as correlation regressions, it is important to include both the reference area and LPRSA data in the same calculation. When performing separate regressions for reference and LPRSA samples, there is a lower probability of finding correlations between benthic invertebrate community data or toxicity data and chemical data. Including both the low COPEC concentrations from the reference area locations with the higher COPEC concentrations from the LPRSA locations, the correlation regression is significantly more powerful, and will be more likely to discern relationships between COPECs and biological impacts. Recalculate the bivariate and multivariate, the correlation regression is significantly more powerful, and will be more likely to discern relationships between COPECs and biological impacts.	Partially acceptable. The CPG put considerable effort into the revised multivariate analyses (summarized in BERA Appendices B and P). The analysis appears to be thorough, and intermediate results support a clear understanding of the methods and results. The analysis also brings to light substantive information with respect to relationships linking toxicity and macroinvertebrate measurement endpoints with sediment contaminant concentrations. These results provide the basis to draw meaningful conclusions with respect to relationships between benthic invertebrate measurement endpoints and chemical contamination. While the results provide the basis to draw meaningful conclusions, the BERA does not yet bring those conclusions to the fore. Appendix A to these BERA comments provides a more in-depth discussion of the rationale behind the selection of appropriate statistical analyses. EPA would like the CPG to add the following text to the BERA conclusions. Additional changes to the results and discussion sections drawn from appendices summarizing factor loadings and other intermediate results will also be needed:

		Recalculate the bivariate and multivariate analyses, keeping the reference area location data and the LPRSA location data together.	*"Benthic invertebrate diversity, survival, and growth are negatively associated with a mixture of metals, DDx, and hexachlorobenzene in the LPRSA sediment. These associations could not be explained through other nonchemical stressors related to environmental conditions and habitat. Through the multivariate analysis, it was found that 10 of 11 measurement endpoints were negatively associated with sediment chemical concentrations. Inclusion of habitat metrics did not explain these patterns in benthic impairment.* *Although commonly reported as a traditional measure of model quality, it is well known that coefficient of multiple determination (R^2) values are generally not indicative of the strength of actual relationships which may not follow the assumptions of fitted models. Low R^2 values (such as those derived through correlation analyses in the BERA) are not necessarily an indicator of a weak relationship, and high R^2 values are not necessarily indicative of a correct model (see Appendix A to these comments).* *The analysis showed that Factor scores including Factor 2 representing a mixture of metals, DDx, and hexachlorobenzene, were negatively associated with low survival and biomass in toxicity tests and with reduced benthic diversity. Mixtures of toxic chemicals were found to co-vary spatially (indicated by groups of high factor loadings on Factor 2) indicating that multiple chemical stressors acting in concert are likely responsible for benthic impairment at the Site. Because multiple COPECs had strong correlations (high loadings) to a small number of factors, it can be concluded that efforts to identify a single contaminant based on field data would be unreliable. Additional lines of evidence related to fate, toxicity, and bioavailability of specific contaminants might be useful to reduce the number of potentially causative compounds. It is likely, however, that benthic impairment is a result of the combined effects of multiple Site-related compounds acting together."*

			See Appendix A entitled EPA comments on the LPRA BERA Revision 2 Draft Report Multivariate Statistical Analyses to this set of comments.
134	Appendix P, Section 2.3.1 Reference Data	Second paragraph: Based on absence of complete SQT data, the Mullica River freshwater reference sample locations were all removed from consideration. This resulted in an absence of non-urban freshwater reference comparisons, and a biased set of comparisons for the freshwater LPRSA sample locations. Per the June 7, 2016 email from Jennifer LaPoma to Robert Law (Subject: SQT Follow Up), the three Mullica River freshwater stations (NJ00-0041, NJ01-0120, and NJ02-0232) should be included as non-urban freshwater reference locations. Revise the BERA to include data from these locations. CPG's July 18, 2016 response letter (from de maximus to Jennifer LaPoma) stated that the data would be included.	Revision is acceptable.
135	Appendix P, Section 2.3.4.1 Quantitative analysis of uncertainty	The Methods paragraph is unclear in its description of how reference area outliers were selected, and which ones were omitted from comparisons with LPRSA locations. The fifth sentence states "The IQR-based outlier removal procedure allows for greater variable in possible reference area data but does not allow for extreme low or high toxicity." This statement appears to say that reference area locations with low toxicity were subject to removal. Clarify the discussion. If any reference locations were omitted for low toxicity, the comparisons will be considered invalid, and the calculations will need to be performed again. The results section is also unclear. For example, the first paragraph says there were 34 acceptable samples from Jamaica Bay with one outlier for low survival (33 useable samples), but Table 2-9 shows a sample size of	Partially acceptable. See Appendix A to these comments.

		26, and Table 3-3 shows a sample size of 31. The tables in Appendix L do not help to decipher which locations were retained for comparison and which were omitted. The tables in Appendix B indicate which locations were retained/omitted, but there is no summary in the BERA to explain the results, nor any interpretation of the results. Revise the text, tables, and Appendix to better describe the outlier removal procedure. Specify which sample locations were retained and which were removed as outliers/unacceptable, and state why each was retained/omitted.	
136	Appendix P, Section 3.1 Methods	Last paragraph. The statistical method used for comparison of LPRSA sample locations to laboratory controls was "a battery of t-tests". Use of t-tests for multi-sample hypothesis testing is not appropriate. As stated in the cited ASTM method (E1367-03), the appropriate statistical method for comparing more than one treatment with a control and in comparing the treatments to one another (as is being done when comparing multiple LPRSA sample locations to multiple reference area locations) should follow the methods outlined in ASTM E1706-05. As stated in Section 15.2.4.9 of ASTM E1706, the appropriate statistical method for multi-sample testing is Analysis of Variance (ANOVA). Using a series of two-sample t-tests for a multi-sample hypothesis is invalid (Zar, 1984). The t statistic is designed for comparison of two sample means, not for multiple sample means. The comparison of ten sample means using t-tests yields a 63% chance of committing a Type I error, and comparison of twenty means yields a 92% chance of Type I error. As the number of means increases, it approaches certainty	Partially acceptable. The CPG put considerable effort into the revised multivariate analyses (summarized in BERA Appendices B and P). The analysis appears to be thorough, and intermediate results support a clear understanding of the methods and results. The analysis also brings to light substantive information with respect to relationships linking toxicity and macroinvertebrate measurement endpoints with sediment contaminant concentrations. These results provide the basis to draw meaningful conclusions with respect to relationships between benthic invertebrate measurement endpoints and chemical contamination. While the results provide the basis to draw meaningful conclusions, the BERA does not yet bring those conclusions to the fore. Appendix A to these BERA comments provides a more in-depth discussion of the rationale behind the selection of appropriate statistical analyses. EPA would like the CPG to add the following text to the BERA conclusions. Additional changes to the results and discussion sections drawn from appendices summarizing factor loadings and other intermediate results will also be needed: "*Benthic invertebrate diversity, survival, and growth are negatively associated with a mixture of metals, DDx, and hexachlorobenzene in the LPRSA sediment. These associations could not be explained*

		that error will be introduced (Zar, J. 1984. Biostatistical Analysis, 2nd edition. Prentice-Hall, Inc.). All statistical analyses of toxicity study batches should be performed using ANOVA. Comparisons should be made between each of the reference areas, as well as to the combined reference areas.	*through other nonchemical stressors related to environmental conditions and habitat. Through the multivariate analysis, it was found that 10 of 11 measurement endpoints were negatively associated with sediment chemical concentrations. Inclusion of habitat metrics did not explain these patterns in benthic impairment.* *Although commonly reported as a traditional measure of model quality, it is well known that coefficient of multiple determination (R^2) values are generally not indicative of the strength of actual relationships which may not follow the assumptions of fitted models. Low R^2 values (such as those derived through correlation analyses in the BERA) are not necessarily an indicator of a weak relationship, and high R^2 values are not necessarily indicative of a correct model (see Appendix A to these comments).* *The analysis showed that Factor scores including Factor 2 representing a mixture of metals, DDx, and hexachlorobenzene, were negatively associated with low survival and biomass in toxicity tests and with reduced benthic diversity. Mixtures of toxic chemicals were found to co-vary spatially (indicated by groups of high factor loadings on Factor 2) indicating that multiple chemical stressors acting in concert are likely responsible for benthic impairment at the Site. Because multiple COPECs had strong correlations (high loadings) to a small number of factors, it can be concluded that efforts to identify a single contaminant based on field data would be unreliable. Additional lines of evidence related to fate, toxicity, and bioavailability of specific contaminants might be useful to reduce the number of potentially causative compounds. It is likely, however, that benthic impairment is a result of the combined effects of multiple Site-related compounds acting together."* See Appendix A to these comments.
137	Appendix P, Section 3.2 Results	The results section includes discussions about differences between the reference area locations and LPRSA locations. As noted in comments above for Appendix P, Section 2.3.4.1, the text and tables do not	Partially acceptable. Revise tables and text to address EPA comments made in Appendix A to these comments.

		give enough detail to determine which locations were included in the comparisons. The figures referenced in Section 3, are simple line drawings of the LPRSA with symbols (not labeled with location ID) indicating which locations were inside/outside the reference envelope. However, there is no suitable explanation of how the comparisons were made, and the associated tables do not indicate which samples were retained or omitted. The dispersal of toxicity test information into the BERA text, Appendix P, Appendix B, and Appendix L make it difficult to agree with any conclusions drawn. A thorough discussion of the reference envelope, how it was derived, which sample locations were used, and how outliers were determined and dealt with is required. Revise the text, tables, and figures to indicate which sample locations were retained/omitted, and why (e.g., show survival/growth numbers). The BERA discussions have to be transparent and complete in order to be found acceptable.	
138	Appendix P, Section 3.2.2.1	Clarification on incorporating the non-urban freshwater sediment, toxicity and benthic community data that is available into the BERA needs to be discussed with the CPG. Multiple parties have provided input on the data that is available from the freshwater Mullica River. However, it appears that there may be no single data set that contains all three segments of the SQT. This will require a separate meeting to discuss the data that are available and the possible methods for inclusion in the BERA.	Revision is acceptable. See Appendix A to these comments.
139	Appendix P, Section 3.2.2.3,	For all five (5) selected urban reference locations upstream of Dundee Dam, the control-normalized *H.*	Revision is acceptable.

	Table 3-4, and Appendix L, Attachment L-1 and Table L-8	*azteca* biomass results ranged from 36% to 47%, indicating substantial toxicity for this endpoint. In the uncertainty section, CPG should add information to explain why the survival and biomass were so low, and how that impacted the interpretation of results.	
140	Appendix P, Section 3.2.4 Summary of Results	First paragraph, first sentence: "…sediment toxicity does not always correspond between endpoints (e.g., toxicity for both species) at the same location". The reason more than one species is used in toxicity testing is because different species have different sensitivities to different COPECs. The fact that a location was toxic to one species and not toxic to another simply highlights that difference. Revise the text to include a discussion of inter-species sensitivities.	Response is acceptable.
141	Appendix P, Section 3.2.5 Uncertainties in comparison to reference data	The uncertainties in comparison to reference data does not include the fact that the reference area locations were sampled and analyzed several years before the LPRSA samples. The fact that the study and reference areas were sampled at different times adds significant uncertainty to all three legs of the SQT (e.g., seasonal disturbances, significant precipitation events/droughts, seasonal/annual variations in benthic invertebrate populations, potential spills or outfalls). Primary among the uncertainties of comparing toxicity test results between reference and LPRSA locations was the fact that the studies were not performed using the same laboratory, lab technicians, lab facilities, test organism source, SRT chart, etc. There can be significant variation in measured toxicity between laboratories, and this was not even mentioned.	Unacceptable. No discussion was added. Revise the text to address EPA's previous comment.

		Revise the text to include a detailed discussion about how reference area locations were selected, and why it was assumed that data from as much as ten years prior to LPRSA sampling would be appropriate. Include a full justification for including the data, and for the comparisons made.	
142	Appendix P, Section 3.2.5 Uncertainties in comparison to reference data	Third bullet: The uncertainties associated with sampling, transport, and storage are mentioned, but a reference is given to another document. Revise the text to include the discussion of uncertainties associated with sampling, transport, and storage.	Partially acceptable. See EPA comment No. 4a.
143	Appendix P, Section 3.2.5 Uncertainties in comparison to reference data	Ninth bullet: Uncertainty is noted from a number of *C. dilutus* larvae that pupated and emerged during the tests. Firstly, this highlights a QA/QC issue with the laboratory performance. Secondly, there is no discussion of how the potential loss of biomass through emergence was handled in the data recording and statistical analysis. Revise the text to explain how many *C. dilutus* emerged, how the data was recorded, and how the statistical analyses were modified to account for the lost biomass from non-mortality-related causes.	Revision is acceptable.
144	Appendix P, page 64, first bullet	Language “The uncertainty associated with the *Chironomus* growth endpoint (i.e., biomass) was greater than that for the survival endpoint (Ingersoll et al. 1995)”) must be removed or revised. *Chironomus* biomass results from the LPRSA were mostly below the biomass results from above the Dundee Dam. For example, 90% of the samples for *Chironomus* biomass control-normalized values from the freshwater section were lower than the 95% LCL on the arithmetic mean from samples above the Dundee Dam. The growth/biomass endpoints represent the primary endpoint for the *Chironomus* sediment toxicity test and should not be diminished.	Revision is acceptable.

		Include TOC measurements from above and below the dam as part of the comparative assessment.	
145	Appendix P, Section 3.2.5.1 Quantitative analysis of uncertainty	Results: The discussions for each reference area and their associated Tables (3-7, 3-8, 3-9, and 3-10) do not give enough detail to support the text. The tables are only summary data, which is of limited use. Revise the text and tables to show which samples were found to be outliers and why.	Revision is acceptable.
146	Appendix P, Section 3.3 Summary	Second paragraph: Delete the second sentence, it is biased and not supported by the data.	Revision is acceptable.
147	Appendix P, Section 4	The toxicity test results should be recalculated using more appropriate statistical methods (ANOVA), in order to better define the relationship between sediment chemistry and toxicity that is discussed in Section 4. Revise the text, tables, and appendices as noted in previous comments, and then recalculate the relationships between sediment chemistry and toxicity. The most appropriate statistical methods can be discussed with EPA's statistician, if CPG needs further direction.	Partially acceptable. The CPG put considerable effort into the revised multivariate analyses (summarized in BERA Appendices B and P). The analysis appears to be thorough, and intermediate results support a clear understanding of the methods and results. The analysis also brings to light substantive information with respect to relationships linking toxicity and macroinvertebrate measurement endpoints with sediment contaminant concentrations. These results provide the basis to draw meaningful conclusions with respect to relationships between benthic invertebrate measurement endpoints and chemical contamination. While the results provide the basis to draw meaningful conclusions, the BERA does not yet bring those conclusions to the fore. Appendix A to these BERA comments provides a more in-depth discussion of the rationale behind the selection of appropriate statistical analyses. EPA would like the CPG to add the following text to the BERA conclusions. Additional changes to the results and discussion sections drawn from appendices summarizing factor loadings and other intermediate results will also be needed: "*Benthic invertebrate diversity, survival, and growth are negatively associated with a mixture of metals, DDx, and hexachlorobenzene in the LPRSA sediment. These associations could not be explained*

			through other nonchemical stressors related to environmental conditions and habitat. Through the multivariate analysis, it was found that 10 of 11 measurement endpoints were negatively associated with sediment chemical concentrations. Inclusion of habitat metrics did not explain these patterns in benthic impairment. *Although commonly reported as a traditional measure of model quality, it is well known that coefficient of multiple determination (R^2) values are generally not indicative of the strength of actual relationships which may not follow the assumptions of fitted models. Low R^2 values (such as those derived through correlation analyses in the BERA) are not necessarily an indicator of a weak relationship, and high R^2 values are not necessarily indicative of a correct model (see Appendix A to these comments).* *The analysis showed that Factor scores including Factor 2 representing a mixture of metals, DDx, and hexachlorobenzene, were negatively associated with low survival and biomass in toxicity tests and with reduced benthic diversity. Mixtures of toxic chemicals were found to co-vary spatially (indicated by groups of high factor loadings on Factor 2) indicating that multiple chemical stressors acting in concert are likely responsible for benthic impairment at the Site. Because multiple COPECs had strong correlations (high loadings) to a small number of factors, it can be concluded that efforts to identify a single contaminant based on field data would be unreliable. Additional lines of evidence related to fate, toxicity, and bioavailability of specific contaminants might be useful to reduce the number of potentially causative compounds. It is likely, however, that benthic impairment is a result of the combined effects of multiple Site-related compounds acting together.”* See Appendix A to these comments.
148	Appendix P, Section 4.1.2 Multivariate analysis – principal	This section goes to great length to perform PCA, but does not yield any significant results. In order for a PCA analysis to be complete, a follow-up factor analysis is required. The factor analysis allows the	Partially acceptable. The CPG put considerable effort into the revised multivariate analyses (summarized in BERA Appendices B and P). The analysis appears to be thorough, and intermediate results support a clear understanding of the methods and results.

	components regression and correlation	investigator to rotate components to see which of them work together, and allows comparisons of COPEC groups (e.g., metals, PCBs, PAH, DDx) alone or comparisons of multiple groups together. Complete the PCA section with a factor analysis.	The analysis also brings to light substantive information with respect to relationships linking toxicity and macroinvertebrate measurement endpoints with sediment contaminant concentrations. These results provide the basis to draw meaningful conclusions with respect to relationships between benthic invertebrate measurement endpoints and chemical contamination. While the results provide the basis to draw meaningful conclusions, the BERA does not yet bring those conclusions to the fore. Appendix A to these BERA comments provides a more in-depth discussion of the rationale behind the selection of appropriate statistical analyses. EPA would like the CPG to add the following text to the BERA conclusions. Additional changes to the results and discussion sections drawn from appendices summarizing factor loadings and other intermediate results will also be needed: "*Benthic invertebrate diversity, survival, and growth are negatively associated with a mixture of metals, DDx, and hexachlorobenzene in the LPRSA sediment. These associations could not be explained through other nonchemical stressors related to environmental conditions and habitat. Through the multivariate analysis, it was found that 10 of 11 measurement endpoints were negatively associated with sediment chemical concentrations. Inclusion of habitat metrics did not explain these patterns in benthic impairment.* *Although commonly reported as a traditional measure of model quality, it is well known that coefficient of multiple determination (R^2) values are generally not indicative of the strength of actual relationships which may not follow the assumptions of fitted models. Low R^2 values (such as those derived through correlation analyses in the BERA) are not necessarily an indicator of a weak relationship, and high R^2 values are not necessarily indicative of a correct model (see Appendix A to these comments).* *The analysis showed that Factor scores including Factor 2 representing a mixture of metals, DDx, and hexachlorobenzene, were*

			negatively associated with low survival and biomass in toxicity tests and with reduced benthic diversity. Mixtures of toxic chemicals were found to co-vary spatially (indicated by groups of high factor loadings on Factor 2) indicating that multiple chemical stressors acting in concert are likely responsible for benthic impairment at the Site. Because multiple COPECs had strong correlations (high loadings) to a small number of factors, it can be concluded that efforts to identify a single contaminant based on field data would be unreliable. Additional lines of evidence related to fate, toxicity, and bioavailability of specific contaminants might be useful to reduce the number of potentially causative compounds. It is likely, however, that benthic impairment is a result of the combined effects of multiple Site-related compounds acting together.” See Appendix A to these comments.

Appendix A: EPA Comments on the LPRSA BERA Revision 2 Draft Report

Multivariate Statistical Analyses

Appendix A: EPA Comments on the LPRSA BERA Revision 2 Draft (December 29, 2017)
Multivariate Statistical Analyses

Comment 1: Model Fit Statistics Versus Relationships

The CPG put considerable effort into the revised multivariate analyses (summarized in BERA Appendices B and P). The analysis appears to be thorough, and intermediate results support a clear understanding of the methods and results. The analysis also brings to light substantive information with respect to relationships linking toxicity and macroinvertebrate measurement endpoints with sediment contaminant concentrations. This information should be brought more clearly into Appendix P, as well as into the main BERA text. The results should be discussed more thoroughly as they relate to the lines of evidence (LOE) and the overall weight of evidence (WOE).

The LPRSA BERA Revision 2 Draft report (dated December 29, 2017) relies on model fit statistics, and in particular it relies on adjusted R-squared (R^2) values as an indication that model fit is poor, and on this basis the actual results of the analyses are downplayed. The emphasis of the text should be revised to include a more in-depth discussion of the relationships that were identified, and their striking consistency across measurement endpoints and data subsets.

For example, Table B-2.7 (reproduced below) shows that for ten of eleven measurement endpoints, the best models demonstrated that biological effects are associated with chemical contamination. The analyses also demonstrated that variation in environmental conditions did not explain these effects related to chemical gradients. When the best models included chemistry and environmental variables, the effects of chemistry were never nullified by environmental variation. This indicates that after adjusting for variation in environmental conditions, benthic invertebrate indices and toxicity indicators (survival and growth effects) were associated with chemical concentrations.

The findings from these analyses provide quantitative evidence of the impacts of sediment contaminants on biological endpoints that is not established elsewhere in the BERA. In a sense, these results represent eleven LOE, ten of which indicate negative biological effects associated with chemical gradients. This should be stated prominently and should figure into the risk characterization. The BERA should conclude that the sediment triad showed that ten of eleven metrics exhibited negative biological effects associated with sediment contaminants, over and above any spatial variation of environmental variables.

Table B2-7. Conclusion of multivariate analyses based on Methods 1 and 2

Benthic Response Variable	Method 1 Model Selection	Method 2 Model Selection	M1 and M2 Conclusions Agree?	Conclusion
Abundance (per m^2)	Full	Habitat-only	No	Models selected are dissimilar. The relative importance of habitat variables and chemical factors on predictions of abundance is unclear. Models are very weak and highly uncertain.
Richness	Limited chemistry	Full	Similar	Models selected are similar in that chemical variables appear to be more important than habitat variables for explaining richness. Models are weak to moderate.
Shannon-Wiener H'	Limited chemistry	Limited chemistry	Yes	Models agree; chemistry factors are more important than habitat variables for explaining Shannon-Wiener H'. Models are weak to moderate.
Pielou's J'	Full	Limited chemistry	Similar	Models are similar, in that chemistry factors are more important than habitat variables for explaining Pielou's J'. Models are very weak.
Swartz's Dominance Index	Limited chemistry	Limited chemistry	Yes	Models agree; chemistry factors are more important than habitat variables for explaining SDI. Models are weak.
Hilsenhoff Biotic Index	Full	Limited chemistry	Similar	Models are similar, in that chemistry factors are more important than habitat variables for explaining HBI. Models are moderate (though relatively strong compared to other models developed herein).
C. dilutus survival	Limited chemistry	Full	Similar	Models are similar, in that chemistry factors are more important than habitat variables for explaining survival. Models are very weak or weak.
C. dilutus biomass	Limited combined	Full	Similar	Models are similar, in that both chemistry factors and habitat variables are important for explaining biomass (though chemistry factors appear to be marginally more important than habitat variables). Models are very weak.
H. azteca survival	Limited combined	Limited combined	Yes	Models are similar, in that chemistry factors are important stressors, and habitat variables appear to reduce effects. Models are very weak or weak.
H. azteca biomass	Limited combined	Limited combined	Yes	Models are similar, in that chemistry factors are important stressors, and habitat variables appear to reduce effects. Models are very weak or weak.
A. abdita survival	Full	Null	No	Models selected are dissimilar. Models are very weak and highly uncertain.

Comment 2: Model Fit Statistics Versus R^2

The BERA relies heavily on discussions of indices of model fit, while spending much less effort interpreting the fitted models and their implications for risk assessment. The BERA emphasizes low R^2 (coefficient of multiple determination) as an indicator that the models are of limited value. EPA disagrees with this assessment.

Although commonly reported as a traditional measure of model quality, it is well known that R^2 values are generally not indicative of model utility. Low R^2 values are not necessarily an indicator of a weak relationship, and high R^2 values are not necessarily indicative of a correct model (for an excellent synopsis and multiple references, see Section 3 of the following lecture notes: http://www.stat.cmu.edu/~cshalizi/mreg/15/lectures/10/lecture-10.pdf).

Figure 1 (below) illustrates one of these problems with using R^2 as an absolute indicator of model utility, when models are fit to data with a narrow range in the predictor. In the figure, one set of data were simulated from a Gompertz survival function and models were fit first to a restricted subset of the data shown as blue circles, yielding $R^2 = 0.04$. The second model was fit to the entire data set resulting in a dramatically higher $R^2 = 0.71$, despite the same model being fit to the data. Both fitted models provide a reasonable fit to the blue data points. The blue line surprisingly provides a reasonable extrapolation beyond the range of blue points. Treating R^2 as an absolute indicator of model utility, as was done in the BERA, would suggest largely dismissing the association between survival and contaminant concentrations as represented by the factor scores.

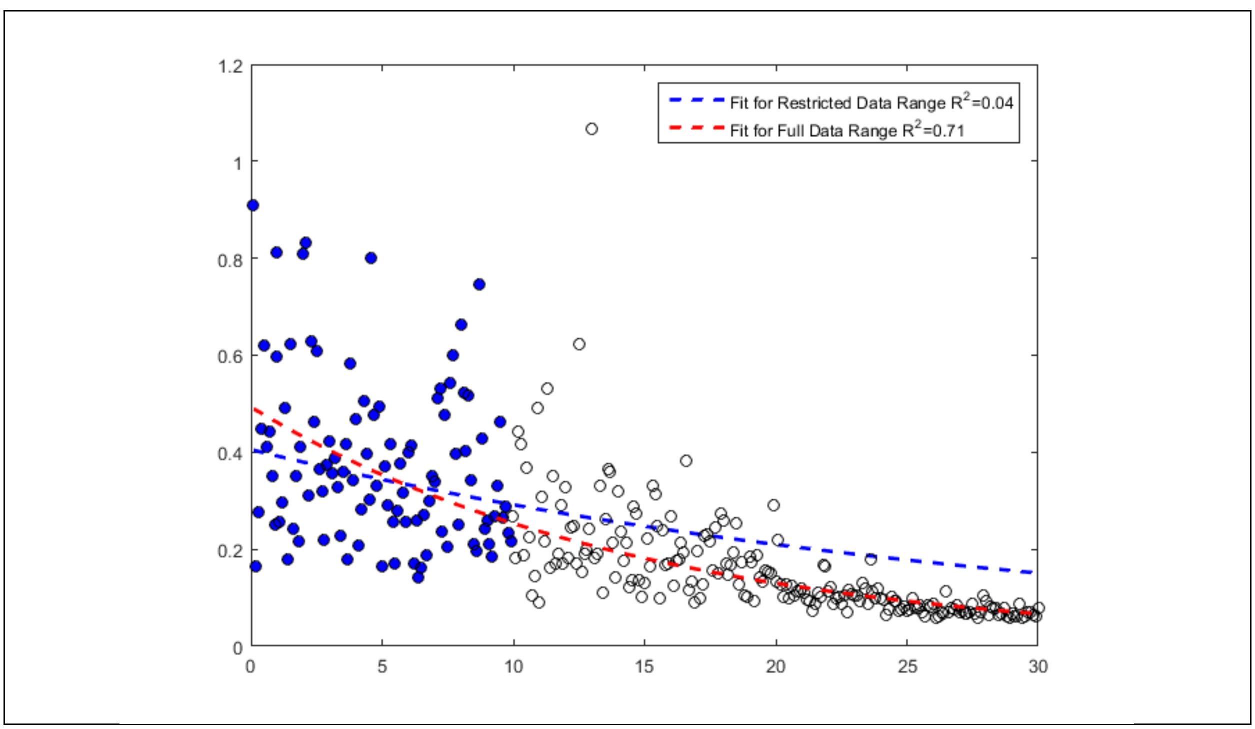


Figure 1. How restricted range of predictor variable influences R^2.

In this analysis, the BERA fits a linear regression model which requires the assumptions of normally distributed errors with constant variance throughout the range of the predictor variables. However, because the data are measured as proportions, there is no expectation that they should follow a normal distribution. Rather, it is expected that variance changes with levels of survival, and the survival is bounded between zero and one (essentially precluding a normal distribution).

The sampling variance of a proportion is a function of the proportion itself. The Figure 2 (below) plot of *Ampelisca abdita* survival against Factor 2 scores[1] (metals and DDx and hexachlorobenzene) shows data that are highly non-normal (top panel) and heteroskedastic (bottom panel). Due to these deviations from assumptions for a linear fit, the low R^2 for a linear function fit to these nonlinear data is expected. The low R^2 in this case reflects the mismatch between the data and fitted model more than information about the relationship between chemical concentrations and biological effects.

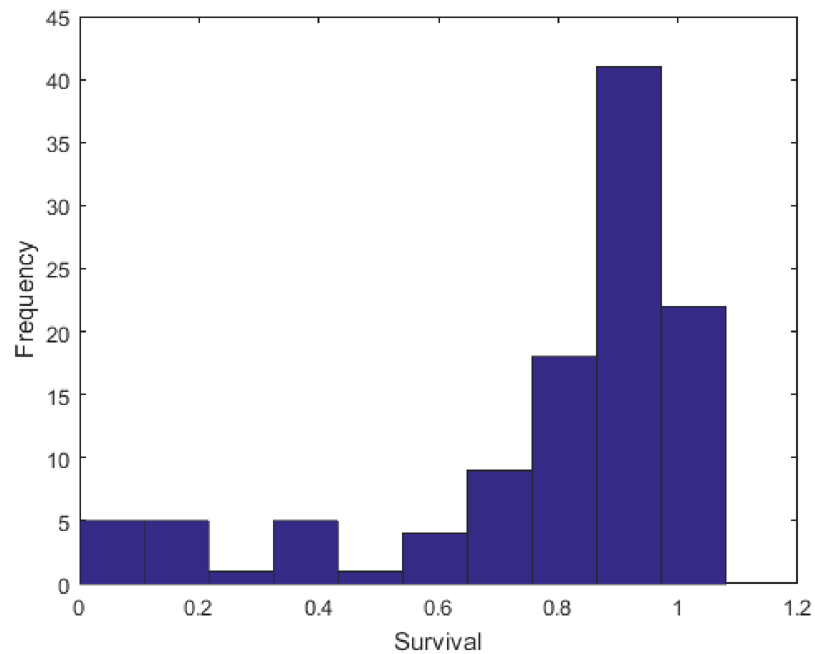
The upper panel in Figure 2 (below) shows that the survival data are highly left skewed, with most toxicity tests yielding values greater than 60% (which in and of itself is important information). Noting that few tests resulted in data with high mortality indicates that estimated associations are likely to be imprecise, due to a lack of variation along the concentration gradient. This suggests that the range of sediment contamination levels evaluated was too narrow to precisely quantify the relationship between COPC concentrations and survival.

The BERA should include a discussion of this situation with emphasis on:

1) A comparison of chemical concentrations at triad locations relative to the overall distribution of chemical concentrations in the larger RI database. Did the triad locations adequately represent the full range of chemical concentrations at the site? An artificially narrow range of chemical concentrations would tend to reduce the power to detect effects and would also result in low R^2 values, irrespective of the strength of the relationships between biotic endpoints and chemical concentrations.

2) The BERA should also discuss how a narrow range of observed survival values would cause a reduction in the power required to detect effects and a correspondingly low R^2, irrespective of the actual dose response relationship that may exist. The experimental design should have included a wider range of chemical concentrations and correspondingly broader distribution of survival values to assure adequate sensitivity of the study to precisely estimate the relationship between concentrations and survival.

[1] Factor scores are the transformed variables obtained from the exploratory factor analysis. Each factor score is a weighted sum of the original variables, where for a particular factor, weights are largest for those variables that are most strongly correlated with each other and the particular factor.



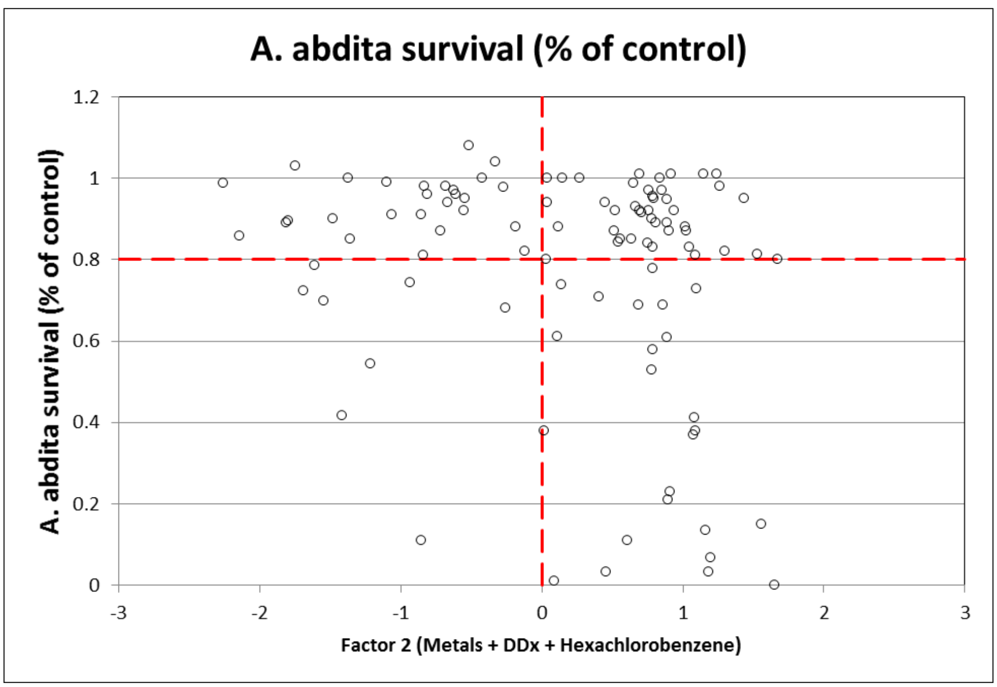


Figure 2. Non-normally distributed survival data (top panel) with heteroskedastic variances (lower panel).

Comment 3: Non-Linear Relationships

The lower panel of Figure 2 (above) also provides important information regarding the nature of the relationship between *A. abdita* survival and Factor 2 (metals and DDx and hexachlorobenzene). The BERA fits a linear model to the data, effectively trying to fit a straight line to the data. It is clear that such a best fit line would only crudely describe the relationship. This plot shows that the proportion of tests exceeding 80% of control is high at the low end of the Factor 2 scale (when metals and DDx and hexachlorobenzene are low) and that for higher levels of Factor 2, the percentage of tests exceeding 80% of control declines. A higher proportion of test results are below the 80% level when the Factor 2 is high. With this increase in Factor 2, the variance of the data also increases with test results ranging from essentially zero survival to 100% of control. Whereas, when Factor 2 is low, virtually all tests resulted in survival greater than 80% of control. This is a highly nonlinear relationship with strongly heteroskedastic errors. The BERA needs to include a discussion of this to illustrate the nature of the relationships that were found and how their nonlinear form tends to reduce measures of model fit, despite obvious underlying relationships establishing associations between biotic metrics and chemical concentrations. Fitting the wrong model (in this case, linear) and then pointing out a low R^2 does not mean there is no relationship. The main conclusion is that the analysis in hand shows that negative effects are associated with chemical stressors. Poor fit for a linear regression is not indicative of the nature of these relationships and should be de-emphasized, in favor of more extensive discussion of the nature of the relationships themselves.

Comment 4: Factor Loadings

The report also fails to adequately discuss and display the factor loadings that were derived from the analyses. With the emphasis on downplaying the importance of the findings, it seems a detailed description of the factor analysis results was omitted. The tabulations provided in spreadsheets form the basis of what needs to be more fully illustrated with figures, and thoroughly discussed in the text. One strength of the exploratory factor analysis (EFA) approach is that results lend themselves to graphical displays to communicate results. The BERA should develop a complete set of figures depicting factor loadings, along with maps of factor scores to illustrate the results (to effectively develop maps to show where the combined concentrations of contaminants are high enough to potentially induce biological effects).

In particular, the EFA provides important information related to risk management options that will become important in the Feasibility Study (FS). For example, the plot in Figure 3 (below) shows that metals contamination, DDx, and hexachlorobenzene tend to be strongly correlated, indicating that they are likely co-located spatially. This information, if verified through careful evaluation, could lead to streamlined selection of preliminary remedial goals (PRGs) on the basis that goals set for one metal (or DDx, or hexachlorobenzene) may also serve to capture other variables that tend to be associated with a single "sentinel" contaminant. Conversely, efforts to identify a single contaminant or a small number of contaminants responsible for effects on benthic invertebrates are unlikely to be successful due to the strong relationships between chemical contaminants. Identifying a single contaminant responsible for effects is unlikely, and remedial option evaluations will need to be based on suites of contaminants which are integrated through the EFA.

The EFA also provides the basis to extrapolate factor scores to the spatially more extensive RI data set identifying areas where Factor 2 is high, which would be indicative of areas with higher probabilities of biological effects. In addition to Factor 2, the BERA identified other factors related to biotic measurement endpoints that should also be discussed similarly (Factor 2 is discussed in this comment as an example).

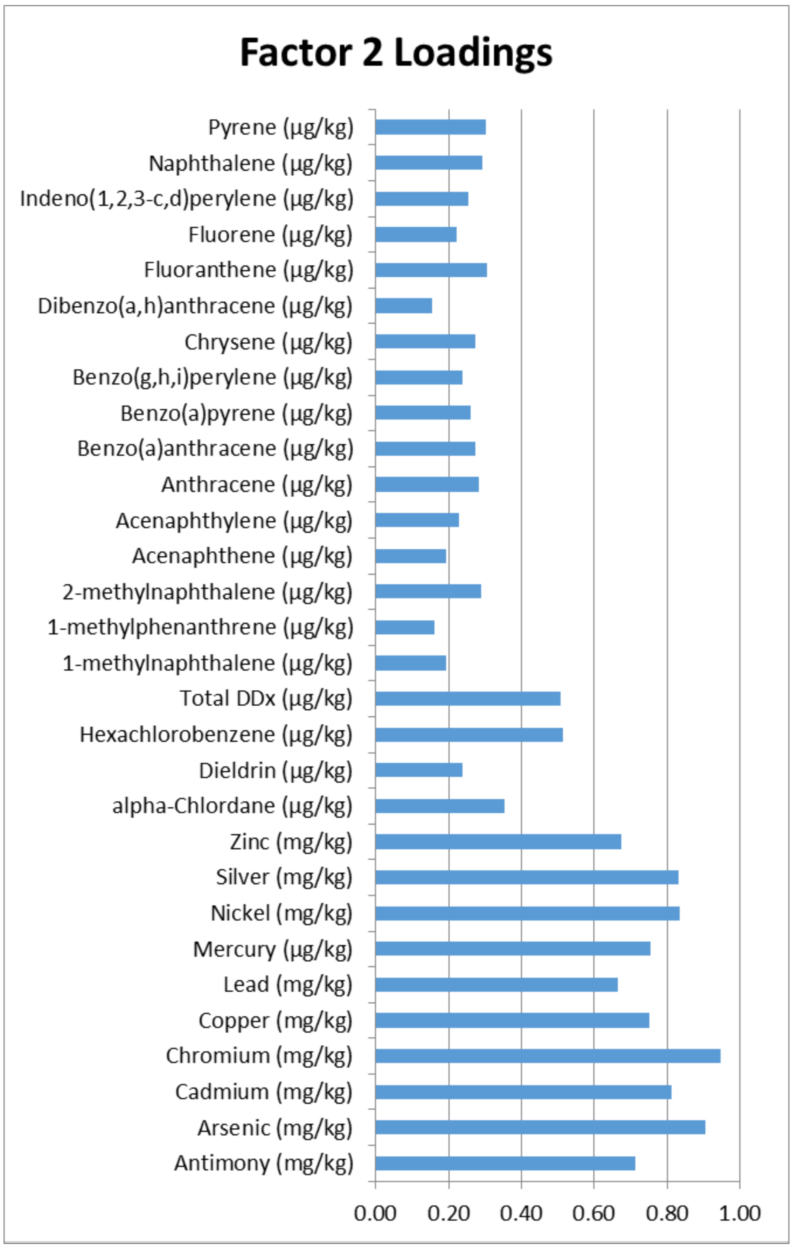


Figure 3: Factor 2 Loadings

Comment 5: Multivariate Analysis and LOE

The BERA should include a discussion of the relationships between the multiple variable analysis and the LOE analyses. It is not clear that the LOE fully capture the nature of the relationships between chemical concentrations and biotic indices. The multivariate analysis integrates chemical and biotic data in a single rigorous analysis in a way that the LOE analyses may not. In this sense, the multivariate analysis could be considered as an alternative to the LOE, or simply as an additional LOE that may be as rigorous, or even more rigorous than other LOE based on indirect scoring and screening of individual metrics without establishing relationships between them. The multivariate analysis takes these data further in establishing links (at least associative, and potentially causal) between chemistry and biotic indices. The BERA should include a thorough discussion of the interactions between LOE analyses and the multivariate analysis. The discussion should also be included in the main BERA text (not relegated to an appendix).

Comment 6: Preliminary Remedial Goals

The EFA shows that benthic invertebrate indices are negatively associated with suites of chemicals, as opposed to one or a few independently acting contaminants. This analysis leads naturally to questions about how preliminary remedial goals (PRGs) should be selected, given that this is usually done by selecting individual contaminants as if they operate independently. The EFA shows that contaminants vary jointly and that their effects on benthic invertebrates cannot be easily separated from one another. While developing quantitative and statistically rigorous links between suites of chemicals and biological effects, the findings of the EFA also complicate PRG selection because the traditional matching of effects thresholds with individual contaminant concentrations ignores the dependence among contaminants.

EPA understands that additional work will be needed to develop a rigorous method for selecting PRGs. One alternative could be to identify threshold levels based on the factor scores most closely tied to benthic invertebrate effects, followed by calculating ranges of multiple contaminant concentrations for key factor constituents that would correspond to factor scores at or below these threshold values. Effectively a Factor Score PRG would be selected and applied to suites of sediment contaminant concentrations. While PRGs have traditionally been based on individual chemicals, there appears to be scientifically defensible reasons to use a Factor-based PRG selection in this case.

If individual chemical PRGs are calculated from Factor-based thresholds, it is important to note that multiple chemical thresholds (PRGs) are likely to be necessary, and that remedial plans would need to manage multiple PRGs. Working directly with the factor scores would reduce the number of thresholds, potentially to a single Factor-based value. It may also be adequate to restrict these efforts to metrics most strongly tied to contaminants, such as the Hilsenhoff Biotic Index in the upper (freshwater) reaches of the LPRSA, and other appropriate metrics in the lower (estuarine) reaches.

As a first step, the BERA should include maps of the three most important factor scores, as well as the "predicted" benthic invertebrate metric values based on contaminant concentrations at the full set of triad and other sampling locations. These maps would serve as starting points for understanding the spatial distribution of impacted sediments, as opposed to only considering the triad locations. Further development of PRGs would be anticipated as part of the FS and may be developed through further evaluations by EPA.